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(54) Title: METHODS AND APPARATUS FOR HEMOSTASIS FOLLOWING ARTERIAL CATHETERIZATION

(57) Abstract: A hemostasis device including a resistance heating element for accelerating hemostasis, a blood resistance sensor and a blood resistance indicator, operative to provide an indication of the resistance at the resistance sensor of blood undergoing hemostasis.

METHODS AND APPARATUS FOR HEMOSTASIS FOLLOWING ARTERIAL CATHETERIZATION

CROSS REFERENCE TO RELATED APPLICATIONS

This application claims the priority of U.S. Application Serial Number 10/358,130, filed February 4, 2003, titled "METHODS AND APPARATUS FOR HEMOSTASIS FOLLOWING ARTERIAL CATHETERIZATION", and U.S. Application Serial Number 10/616,887, filed July 10, 2003, titled "METHODS AND APPARATUS FOR HEMOSTASIS FOLLOWING ARTERIAL CATHETERIZATION".

FIELD OF THE INVENTION

The present invention relates to catheterization systems and methodologies generally and more particularly to post-catheterization closure.

BACKGROUND OF THE INVENTION

Various techniques are known for arterial catheterization. Following arterial catheterization, it is necessary to promote hemostasis quickly and without undue hardship for the patient.

Applicant's U.S. Patents 5,728,134 and 6,048,358, and Published PCT Patent Applications WO 98/11830 and WO 00/02488 describe methods and apparatus for hemostasis that greatly simplify hemostasis and thus greatly reduce patient discomfort following arterial catheterization. These patent documents, the disclosures of which are hereby incorporated by reference, and the prior art referenced therein are considered to represent the state of the art.

SUMMARY OF THE INVENTION

The present invention seeks to provide improved systems and methodologies for post-catheterization closure.

There is thus provided in accordance with a preferred embodiment of the present invention a hemostasis device including a resistance heating element for accelerating hemostasis, a blood resistance sensor and a blood resistance indicator, operative to provide an indication of the resistance at the resistance sensor of blood undergoing hemostasis.

In accordance with another preferred embodiment of the present invention the hemostasis device also includes a power supply connected to the resistance heating element, the resistance sensor and the resistance indicator. Additionally, the power supply is operative to supply a relatively high level current to the resistance heating element. Alternatively, the power supply is operative to supply a relatively low level current to the resistance sensor.

There is also provided in accordance with another preferred embodiment of the present invention a method for accelerating hemostasis of an artery of a patient having a puncture after arterial catheterization, the method including the steps of following arterial catheterization, introducing a hemostasis device, such that a forward end of the hemostasis device lies exterior of the artery adjacent the puncture, accelerating hemostasis by heating tissue in the vicinity of the puncture, thereby shortening the time required for hemostasis and following hemostasis, removing the hemostasis device from the patient.

In accordance with another preferred embodiment of the present invention the method also includes inserting a catheter introducer into the artery prior to the arterial catheterization and wherein following the arterial catheterization, the hemostasis device is introduced through the catheter introducer. In accordance with yet another preferred embodiment of the present invention the method also includes measuring the conductivity of blood in the vicinity of the puncture during hemostasis.

There is further provided in accordance with another preferred embodiment of the present invention a method for monitoring the progress of hemostasis of an artery of a patient having a puncture after arterial catheterization, the

method including the steps of following arterial catheterization, introducing a hemostasis device, such that a forward end of the hemostasis device lies exterior of the artery adjacent the puncture, during hemostasis, measuring the heat conductivity of blood in the vicinity of the puncture, thereby to provide an output indication of the progress of hemostasis and following hemostasis, removing the hemostasis device from the patient.

In accordance with another preferred embodiment of the present invention the method also includes the step of inserting into an artery a catheter introducer prior to arterial catheterization and wherein following the arterial catheterization, the hemostasis device is introduced through the catheter introducer.

In accordance with yet another preferred embodiment of the present invention the method also includes inflating a balloon to block the puncture, prior to the hemostasis. Additionally, the method also includes deflating the balloon prior to removing the hemostasis device.

There is still further provided in accordance with another preferred embodiment of the present invention a hemostasis device including a main shaft, at least one balloon mounted on the main shaft and at least one electrode, mounted on the main shaft and being operable to supply an electric current suitable for causing hemostasis.

In accordance with another preferred embodiment of the present invention the at least one balloon includes at least one anchor balloon, disposed at an end of the main shaft and at least one peripheral balloon, disposed at a location along the main shaft exterior to a wall of the main shaft. In accordance with still another preferred embodiment of the present invention the at least one peripheral balloon and a wall of an artery are configured to delimit a region which is subject to hemostasis.

In accordance with yet another preferred embodiment of the present invention the hemostasis device also includes an electrical power source and a control module. In accordance with another preferred embodiment of the present invention the power source is an RF power supply. Preferably, the RF power supply is operative to supply electrical power at RF frequencies within a range of 0.1 - 10 watts at up to 25 volts. In accordance with another preferred embodiment of the present invention the control module is operative to measure at least one of electrical current, blood resistance and blood temperature. Additionally or alternatively, the control module is operative to

adjust the power supplied by the power source based on at least one measurement.

In accordance with still another preferred embodiment of the present invention the at least one electrode includes a pair of electrodes.

There is even further provided in accordance with another preferred embodiment of the present invention a method for producing hemostasis at an artery of a patient having a puncture following arterial catheterization including introducing a hemostasis device including at least one electrode into the vicinity of the puncture, supplying an electric current to the at least one electrode, thereby heating a volume of blood in the vicinity of the puncture, cansing hemostasis and subsequently removing the hemostasis device from the patient.

In accordance with another preferred embodiment of the present invention introducing includes introducing via a catheter introducer. Additionally or alternatively, the introducing also includes inflating an anchor balloon attached to an end of the hemostasis device. In accordance with another preferred embodiment of the present invention the introducing includes inflating a peripheral balloon. Additionally, the removing the hemostasis device includes deflating the peripheral balloon.

In accordance with still another preferred embodiment of the present invention the introducing includes positioning the at least one electrode in close proximity to a volume of blood.

In accordance with another preferred embodiment of the present invention the supplying includes supplying electrical power at RF frequencies. Additionally, the electrical power includes electrical power in the range of 0.1 - 10 watts at up to 25 volts. Alternatively or additionally, the supplying also includes adjusting the electric current based on a feedback measurement.

There is also provided in accordance with yet another preferred embodiment of the present invention a hemostasis device including a main shaft, at least one balloon mounted on the main shaft adjacent an end thereof and a hemostasis agent supply conduit operative to supply a hemostasis agent at a location at the end of the main shaft beyond the at least one balloon.

In accordance with another preferred embodiment of the present invention the hemostasis device also includes at least one heating assembly operative to provide heating at the location. In accordance with still another preferred embodiment

of the present invention the at least one heating assembly includes at least one electrode disposed adjacent the location. In accordance with another preferred embodiment of the present invention the at least one electrode is disposed interiorly of the at least one balloon. Alternatively, the at least one electrode is disposed exteriorly of the at least one balloon. In accordance with yet another preferred embodiment of the present invention the at least one heating assembly includes an electrical resistive heating element. In accordance with still another preferred embodiment of the present invention the electrical resistive heating element is disposed within the at least one balloon.

There is further provided in accordance with still another preferred embodiment of the present invention a hemostasis device including a main shaft, at least one balloon mounted on the main shaft adjacent an end thereof and at least one RF electrode located at a location at an end of the main shaft beyond the at least one balloon.

In accordance with another preferred embodiment of the present invention the hemostasis device also includes a hemostasis agent supply conduit operative to supply a hemostasis agent at a location at an end of the main shaft beyond the at least one balloon.

In accordance with yet another preferred embodiment of the present invention the at least one RF electrode is disposed interiorly of the at least one balloon. Alternatively, the at least one RF electrode is disposed exteriorly of the at least one balloon.

There is even further provided in accordance with yet another preferred embodiment of the present invention a hemostasis device including a main shaft, at least one balloon mounted on the main shaft adjacent an end thereof and at least one resistive heating element located at a location at an end of the main shaft beyond the at least one balloon.

In accordance with another preferred embodiment of the present invention the hemostasis device also includes a hemostasis agent supply conduit operative to supply a hemostasis agent at a location at an end of the main shaft beyond the at least one balloon.

In accordance with yet another preferred embodiment of the present invention the at least one resistance heating element is disposed interiorly of the at least least

one balloon.

There is still further provided in accordance with another preferred embodiment of the present invention a method for producing hemostasis at an artery of a patient having a puncture following arterial catheterization including introducing a hemostasis device including at least one balloon mounted adjacent an end of a shaft to a location in the vicinity of the puncture and supplying a hemostasis agent to the location at the end of the shaft beyond the at least one balloon.

In accordance with still another preferred embodiment of the present invention the method also includes providing heating at the location. In accordance with another preferred embodiment of the present invention the providing heating includes locating at least one electrode adjacent the location. Additionally, the at least one electrode is disposed interiorly of the at least one balloon. Alternatively, the at least one electrode is disposed exteriorly of the at least one balloon. In accordance with yet another preferred embodiment of the present invention the providing heating includes providing electrical resistive heating.

There is also provided in accordance with another preferred embodiment of the present invention a method for producing hemostasis at an artery of a patient having a puncture following arterial catheterization including introducing a hemostasis device including at least one balloon mounted adjacent an end of a shaft to a location in the vicinity of the puncture and operating at least one RF electrode at the location at the end of the main shaft beyond the at least one balloon.

In accordance with another preferred embodiment of the present invention the method also includes supplying a hemostasis agent to the location at the end of the shaft beyond the at least one balloon. In accordance with yet another preferred embodiment of the present invention the at least one RF electrode is disposed interiorly of the at least one balloon. Alternatively, the at least one RF electrode is disposed exteriorly of the at least one balloon.

There is further provided in accordance with yet another preferred embodiment of the present invention a method for producing hemostasis at an artery of a patient having a puncture following arterial catheterization including introducing a hemostasis device including at least one balloon mounted adjacent an end of a shaft to a location in the vicinity of the puncture and operating at least one resistance heating

element at the location at an end of the shaft beyond the at least one balloon.

In accordance with another preferred embodiment of the present invention the method also includes supplying a hemostasis agent to the location at the end of the shaft beyond the at least one balloon.

In accordance with still another preferred embodiment of the present invention the at least one resistance heating element is disposed interiorly of the at least one balloon.

BRIEF DESCRIPTION OF THE DRAWINGS

The present invention will be understood and appreciated more fully from the following detailed description, taken in conjunction with the drawings in which:

Figs. 1A and 1B are simplified pictorial illustrations of respective first and second modes of operation of a hemostasis device constructed and operative in accordance with a preferred embodiment of the present invention;

Fig. 2 is a simplified pictorial illustration of the hemostasis device of Figs. 1A and 1B during hemostasis;

Figs. 3A and 3B are graphs illustrating the typical conductivity levels measured by the hemostasis device when used in the operating modes shown in Figs. 1A and 1B, respectively;

Fig. 4 is a simplified illustration of a hemostasis device constructed and operative in accordance with a preferred embodiment of the present invention;

Figs. 5A, 5B, 5C, 5D, 5E, 5F, 5G, 5H and 5I are simplified illustrations of the operation of the apparatus of Fig. 4 in a patient treatment context;

Fig. 6 is a simplified illustration of a hemostasis device constructed and operative in accordance with another preferred embodiment of the present invention;

Figs. 7A, 7B, 7C, 7D, 7E, 7F, 7G, 7H, 7I and 7J are simplified illustrations of a hemostasis device constructed and operative in accordance with another preferred embodiment of the present invention and various stages of its operation in a patient treatment context;

Figs. 8A, 8B, 8C and 8D are simplified illustrations of four different states of inflation of the hemostasis device of Figs. 7A-7J;

Figs. 9A, 9B, 9C, 9D, 9E, 9F, 9G, 9H, 9I and 9J are simplified illustrations of a hemostasis device constructed and operative in accordance with another preferred embodiment of the present invention and various stages of its operation in a patient treatment context;

Figs. 10A, 10B, 10C and 10D are simplified illustrations of four different states of inflation of the hemostasis device of Figs. 9A-9J;

Figs. 11A, 11B, 11C, 11D, 11E, 11F, 11G, 11H, 11I and 11J are

simplified illustrations of a hemostasis device constructed and operative in accordance with another preferred embodiment of the present invention and various stages of its operation in a patient treatment context;

Figs. 12A, 12B, 12C and 12D are simplified illustrations of four different states of inflation of the hemostasis device of Figs. 11A-11J;

Figs. 13A, 13B, 13C, 13D, 13E, 13F, 13G, 13H, 13I and 13J are simplified illustrations of a hemostasis device constructed and operative in accordance with another preferred embodiment of the present invention and various stages of its operation in a patient treatment context;

Figs. 14A, 14B, 14C and 14D are simplified illustrations of four different states of inflation of the hemostasis device of Figs. 13A-13J;

Figs. 15A, 15B, 15C, 15D, 15E, 15F, 15G, 15H, 15I and 15J are simplified illustrations of a hemostasis device constructed and operative in accordance with another preferred embodiment of the present invention and various stages of its operation in a patient treatment context; and

Figs. 16A, 16B, 16C and 16D are simplified illustrations of four different states of inflation of the hemostasis device of Figs. 15A-15J.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

Reference is now made to Figs. 1A and 1B, which are simplified pictorial illustrations of a preferred embodiment of a hemostasis device in respective first and second modes of operation.

As seen in Fig. 1A, a hemostasis device 10 is inserted into a catheter introducer 11, following arterial catheterization and withdrawal of a catheter (not shown), such that a forward end 12 of the hemostasis device 10 lies adjacent to and outside a puncture 14 in an artery 16. At least one external balloon 18 is preferably disposed adjacent catheter introducer 11 and is shown in an inflated orientation, wherein the balloon 18 forms a skirt surrounding and sealing puncture 14 from the tissue external thereto. At this stage blood normally fills artery 16 as well as puncture 14, as well as the annular volume 20 surrounded by balloon 18 adjacent puncture 14 and forward end 12.

In accordance with another preferred embodiment of the present invention, the at least one balloon 18 need not be provided.

In accordance with a preferred embodiment of the present invention, a resistance element 22 is disposed at a forward edge 24 of the forward end 12, and is coupled in series with an external power supply 26 via conductors 28, which typically extend along the length of the hemostasis device 10. Preferably, the series connection includes a resistance indicator 30, which provides an indication of the resistance at a resistance sensor 32.

As seen in Fig. 1A, a low level current, typically less than 0.1 ampere, is provided by external power supply 26 to enable the resistance indicator 30 to monitor the progress of hemostasis, to allow for timely removal of catheter introducer 11 and hemostasis device 10 from the patient.

It is appreciated that the heat conductivity of the blood in liquid form is measurably different from that of a blood clot formed during hemostasis, as will be described hereinbelow with reference to Figs. 3A and 3B.

Fig. 1B illustrates the hemostasis device of Fig. 1A in a second preferred mode of operation. As shown in Fig. 1B, a high level electrical current, typically greater than 0.1 ampere, is supplied via the external power supply 26 to resistance element 22.

The provision of this current causes heating of the blood adjacent to the resistance element 22 and provides for accelerated hemostasis. The provision of resistance indicator 30, connected to resistance sensor 32, enables the monitoring of the progress of the accelerated hemostasis, to allow for regulation of the current provided to resistance element 22 over time, and to allow timely removal of catheter introducer 11 and hemostasis device 10 from the patient.

It is appreciated that the heat conductivity of the blood in liquid form is measurably different from that of a blood clot formed during hemostasis, as will be described hereinbelow with reference to Figs. 3A and 3B.

Reference is now made to Fig. 2, which is a simplified pictorial illustration of hemostasis device 10 of Figs. 1A and 1B during hemostasis.

Fig. 2 shows the hemostasis device 10 of Figs. 1A and 1B and illustrates the different heat conductivity of the blood during the various stages of hemostasis. As seen in Fig. 2, the blood flowing through the artery 16 and adjacent the puncture 14 in the artery is in liquid form, where its heat conductivity is greater than that of the blood 40 which has begun to coagulate. Blood 40 is in a viscous form, which has a heat conductivity greater than that of the blood 42, which has already begun to solidify into a blood clot. Resistance sensor 32 is thus able to measure the process of coagulation by measuring the heat conductivity of the adjacent blood.

Reference is now made to Figs. 3A and 3B, which are graphs illustrating the typical conductivity levels measured by the catheter introducer assembly when used in the operating modes shown in Figs. 1A and 1B, respectively.

Fig 3A shows the heat conductivity of the blood over time, in the mode of operation illustrated in Fig. 1A, where the blood is in a liquid form at time T_0, with relatively high heat conductivity, where the heat conductivity decreases gradually over time as the blood forms a clot at time T_H.

Fig. 3B shows the heat conductivity of the blood over time, in the mode of operation illustrated in Fig. 1B, where the blood is heated to accelerate clotting. As seen in Fig. 3B, the heat conductivity begins at time T_0 in a liquid form with relatively high heat conductivity, which decreases rapidly as the blood is heated and the clotting occurs at an accelerated rate. Fig. 3B also shows the heat conductivity curve over time shown in Fig. 3A, which clearly illustrates the accelerated hemostasis described in

reference to Fig. 1B hereinabove, where T_{HA} is the accelerated hemostasis time and T_H is the non-accelerated hemostasis time.

Reference is now made to Fig. 4, which is a simplified illustration of a hemostasis device 100 for producing hemostasis following arterial catheterization, in accordance with a preferred embodiment of the present invention. The hemostasis device 100 is suitable for insertion via a conventional catheter introducer (not shown) following completion of catheterization and removal of the catheter from the catheter introducer.

In accordance with a preferred embodiment of the present invention, hemostasis device 100 comprises a main shaft 102, which has an outer wall 104 and preferably includes at least three bores. A first bore, designated generally by reference numeral 110, extends along the main shaft 102 to an anchor balloon inflation location 112. A second bore 120 extends along the shaft 102 to a peripheral balloon inflation location 122. A third bore, designated generally by reference number 130, contains an electrocoagulation heating device 132 connected to an electrical power source and control module 134 by a connector 136.

Disposed at an end of main shaft 102 at anchor balloon inflation location 112 is an anchor balloon 140. Anchor balloon 140 is selectably inflated at anchor balloon inflation location 112, as shown in Fig. 5C, via a stopcock 142 and associated conduit 144 in fluid communication with main shaft 102 via a passageway 146 formed in a head element 150. Head element 150 is fixed to main shaft 102 at an end thereof opposite the end at which anchor balloon 140 is located.

Disposed adjacent the end of second bore 120 in fluid communication with peripheral balloon inflation location 122, exterior of wall 104, is a peripheral balloon 160. Peripheral balloon 160 is selectably inflated at peripheral balloon inflation location 112, as shown in Fig. 5E, via second bore 120, via a stopcock 162 and associated conduit 164 that communicate with second bore 120 via a passageway 166 formed in head element 150.

In accordance with a preferred embodiment of the present invention, electrocoagulation heating device 132 comprises an electrical conductor 170 connected to an electrocoagulation electrode 176 at an extreme end 178 of third bore 130. A pair of electrical cables 180 and 182 extends from electrical power source and control

module 134. In the illustrated embodiment, electrical cable 180 serves as a power supply cable and is connected to electrocoagulation heating device 132 by connector 136. Electrical cable 182 serves as a return current cable and is preferably connected to an electrode 184 attached to a body of a patient.

Electrical power source and control module 134 preferably comprises a power supply, preferably an RF power supply source 186, including a feedback measurement circuit 188. The feedback measurement circuit 188 is preferably operative to measure current, blood resistance or blood temperature and thereby determine progress of hemostasis. The electrical power source and control module 134 also preferably includes a microprocessor 190, operative to adjust the power supplied to hemostasis device 100 according to the blood temperature or other feedback measurement received from feedback measurement circuit 188, in order to achieve optimal coagulation of the blood.

In accordance with a preferred embodiment of the present invention an operator actuation switch 192 is connected along electrical cable 180. In accordance with another preferred embodiment, switch 192 may be obviated and electrical cable 180 connected directly to connector 136.

Reference is now made to Figs. 5A – 5I, which illustrate various steps in a preferred mode of operation of the apparatus of Fig. 4.

Fig. 5A illustrates the hemostasis device 100 about to be inserted into an artery 200 via a conventional catheter introducer assembly 202, following completion of a catheterization procedure and withdrawal of a catheter (not shown) from the catheter introducer assembly 202. The catheter introducer assembly 202 conventionally includes a catheter introducer sheath 204.

Fig. 5B shows the hemostasis device 100 inserted into the catheter introducer assembly 202 such that the outer end of the main shaft 102 extends into the artery 200 well beyond the end of catheter introducer sheath 204. As shown with particularity in Fig. 5B, at this stage both anchor balloon 140 and peripheral balloon 160 are deflated.

Reference is now made to Fig. 5C, which shows initial inflation of the anchor balloon 140, preferably by use of a syringe 220, communicating with first bore 110 via the interior of head element 150, stopcock 142 and associated conduit 144. The

inflated anchor balloon 140 preferably has a cusp-type configuration as seen with particularity in Fig. 5C.

Following inflation of the anchor balloon 140, the catheter introducer assembly 202 and the hemostasis device 100 are both withdrawn, such that the catheter introducer sheath 204 is removed from artery 200 only when the anchor balloon 140 already engages the interior wall of artery 200 in sealing engagement with the aperture in the artery 200 through which the catheter introducer sheath 204 is withdrawn and through which the main shaft 102 presently extends. This stage is shown in Fig. 5D.

As seen in Fig. 5E, initial inflation of the peripheral balloon 160 is effected, preferably by use of a syringe 240 communicating with second bore 120 via head element 150, stopcock 162 and associated conduit 164.

Thereafter, as seen in Fig. 5F, the anchor balloon 140 is deflated, preferably by operation of syringe 220, communicating with first bore 110 via the interior of head element 150, stopcock 142 and associated conduit 144, and the peripheral balloon 160 is inflated, which preferably causes the extreme end of the main shaft 102 to be withdrawn from the artery 200 to a location lying just outside the artery wall. As seen in Fig. 5F, peripheral balloon 160 is preferably designed to allow a limited volume of blood to collect outside of the artery wall after the anchor balloon 140 is deflated. This volume of blood is located in a region, indicated by reference numeral 250, delimited by the engagement of peripheral balloon 160 with the artery wall.

At this stage, electric power is supplied to the electrode 176 to provide heating of the blood in region 250, causing coagulation thereof, as seen in Fig. 5G. In accordance with the illustrated embodiment of Fig. 4 and as shown in Fig. 5G, the electric power is provided by actuation of switch 192. In accordance with another preferred embodiment, switch 192 is obviated, and the electric power is provided by connecting electrical cable 180 (Fig. 4) directly to connector 136.

Preferably, the amount of electrical power supplied along electrical cable 180 (Fig. 4) from electrical power source and control module 134 to the electrocoagulation electrode 176 is between 0.1 - 10 watts at up to 25 volts at RF frequencies.

Once acceptable hemostasis has occurred in region 250, the peripheral balloon 160 is deflated, as shown in Fig. 5H, preferably by operation of syringe 240

communicating with second bore 120 via head element 150, stopcock 162 and associated conduit 164.

Thereafter, the hemostasis device 100 is entirely withdrawn from the patient, leaving a region 260 of hemostasis outside of artery 200, as shown in Fig. 5L.

Reference is now made to Fig. 6, which is a simplified illustration of a hemostasis device constructed and operative in accordance with another preferred embodiment of the present invention. The embodiment of Fig. 6 is similar to that of Fig. 4, except as described hereinbelow. Elements that occur in both embodiments are identified by the same reference numerals.

In the embodiment of Fig. 6, electrocoagulation heating device 132 comprises a pair of separate electrical conductors 300 extending along third bore 130 connecting electrical power source and control module 134 to a pair of electrocoagulation electrodes 302 at end 178 of third bore 130. Electrical cables 180 and 182 are both connected to electrocoagulation heating device 132 by connector 136. The illustrated embodiment shows connector 136 directly connected to electrical cables 180 and 182.

In the embodiment of Fig. 6, the electrodes 302 may be arranged in mutual coaxial arrangement or in mutual side-by-side arrangement or in any other suitable arrangement.

Reference is now made to Figs. 7A, 7B, 7C, 7D, 7E, 7F, 7G, 7H, 7I and 7J, which are simplified illustrations of a hemostasis device constructed and operative in accordance with another preferred embodiment of the present invention and various stages of its operation in a patient treatment context, and to Figs. 8A, 8B, 8C and 8D, which are simplified illustrations of four different states of inflation of the hemostasis device.

Fig. 7A shows a hemostasis device 400 for producing hemostasis following arterial catheterization in accordance with another preferred embodiment of the present invention. The hemostasis device 400 is suitable for insertion via a conventional catheter introducer (not shown) following completion of catheterization and removal of the catheter from the catheter introducer.

In accordance with a preferred embodiment of the present invention, hemostasis device 400 comprises a main shaft 402, which has first and second lumens

404 and 406. First lumen 404 extends along the main shaft 402 to an anchor balloon inflation location 412. Second lumen 406 extends along the shaft 402 to a peripheral balloon inflation location 422.

Disposed at an end of main shaft 402 at anchor balloon inflation location 412 is an anchor balloon 440. Anchor balloon 440 is selectably inflated, as shown in Figs 8A - 8D, via a stopcock 442 and associated conduit 444 in fluid communication with main shaft 402 via a passageway 446 formed in a head element 450. Head element 450 is fixed to main shaft 402 at an end thereof opposite the end at which anchor balloon 440 is located.

Disposed adjacent the end of main shaft 402, in fluid communication with peripheral balloon inflation location 422, exterior of an outer wall 452 thereof, is a peripheral balloon 460. Peripheral balloon 460 is selectably inflated, as shown in Figs. 8A - 8D, via second lumen 406, via a stopcock 462 and associated conduit 464 that communicate with second lumen 406 via a passageway 466 formed in head element 450.

In accordance with a preferred embodiment of the present invention, a coagulant agent supply conduit 470 extends through the first lumen 404 and through a bore 472 formed along the length of head element 450. Coagulant agent supply conduit 470 communicates at one end thereof with a volume defined by inflation of the peripheral balloon 460, between the balloon 460 and the outer surface of an adjacent artery (not shown). At its opposite end, conduit 470 communicates with a supply of coagulant agent (not shown) via a stopcock 474 and associated conduit 476.

Figs. 7B – 7J illustrate various steps in a preferred mode of operation of the apparatus of Fig. 7A. Fig. 7B illustrates the hemostasis device 400 about to be inserted into an artery 500 via a conventional catheter introducer assembly 502, following completion of a catheterization procedure and withdrawal of a catheter (not shown) from the catheter introducer assembly 502. The catheter introducer assembly 502 conventionally includes a catheter introducer sheath 504.

Fig. 7C shows the hemostasis device 400 inserted into the catheter introducer assembly 502 such that the outer end of the main shaft 402 extends into the artery 500 well beyond the end of catheter introducer sheath 504. As shown with particularity in Fig. 7C, at this stage both anchor balloon 440 and peripheral balloon 460

are deflated, as seen clearly in Fig. 8A.

Reference is now made to Fig. 7D, which shows initial inflation of the anchor balloon 440, preferably by use of a syringe 520, communicating with first lumen 404 via passageway 446 extending through the interior of head element 450, stopcock 442 and associated conduit 444. The inflated anchor balloon 440 preferably has a cusp-type configuration as seen with particularity in Figs. 7D and 8B.

Following inflation of the anchor balloon 440, the catheter introducer assembly 502 and the hemostasis device 400 are both withdrawn, such that the catheter introducer sheath 504 is removed from artery 500 only when the anchor balloon 440 already engages the interior wall of artery 500 in sealing engagement with the aperture in the artery 500 through which the catheter introducer sheath 504 is withdrawn and through which the main shaft 402 presently extends. This stage is shown in Fig. 7E.

As seen in Figs. 7F and 8C, initial inflation of the peripheral balloon 460 is effected, preferably by use of a syringe 540 communicating with second lumen 406 via passageway 466 in head element 450, stopcock 462 and associated conduit 464.

Thereafter, as seen in Figs. 7G and 8D, the anchor balloon 440 is deflated, preferably by operation of syringe 520, communicating with first lumen 404 via passageway 446 in head element 450, stopcock 442 and associated conduit 444, and the peripheral balloon 460 remains fully inflated, which preferably causes the extreme end of the main shaft 402 to be withdrawn from the artery 500 to a location lying just outside the artery wall. As seen in Fig. 7G, peripheral balloon 460 is preferably designed to allow a limited volume of blood to collect outside of the artery wall after the anchor balloon 440 is deflated. This volume of blood is located in a region, indicated by reference numeral 550, delimited by the engagement of peripheral balloon 460 with the artery wall.

At this stage, a coagulant agent is preferably supplied to the volume of blood at region 550, between the balloon 460 and the outer surface of artery 500. The coagulant agent is supplied to region 550 by conduit 470 from a supply of coagulant agent 552 via stopcock 474 and associated conduit 476, as shown in Fig. 7H.

Once acceptable hemostasis has occurred in region 550, the peripheral balloon 460 is deflated, as shown in Figs 7I and 8A, preferably by operation of syringe 540, communicating with second lumen 406 via passageway 466 in head element 450,

stopcock 462 and associated conduit 464.

Thereafter, the hemostasis device 400 is entirely withdrawn from the patient, leaving a region 560 of hemostasis outside of artery 500, as shown in Fig. 7J.

Reference is now made to Figs. 9A, 9B, 9C, 9D, 9E, 9F, 9G, 9H, 9I and 9J, which are simplified illustrations of a hemostasis device constructed and operative in accordance with still another preferred embodiment of the present invention and various stages of its operation in a patient treatment context, and to Figs. 10A, 10B, 10C and 10D, which are simplified illustrations of four different states of inflation of the hemostasis device.

Fig. 9A shows a hemostasis device 600 for producing hemostasis following arterial catheterization, in accordance with yet another preferred embodiment of the present invention. The hemostasis device 600 is suitable for insertion via a conventional catheter introducer (not shown) following completion of catheterization and removal of the catheter from the catheter introducer.

In accordance with a preferred embodiment of the present invention, hemostasis device 600 comprises a main shaft 602, which has first and second lumens 604 and 606. First lumen 604 extends along the main shaft 602 to an anchor balloon inflation location 612. Second lumen 606 extends along the shaft 602 to a peripheral balloon inflation location 622.

Disposed at an end of main shaft 602 at anchor balloon inflation location 612 is an anchor balloon 640. Anchor balloon 640 is selectably inflated, as shown in Figs 10A - 10D, via a stopcock 642 and associated conduit 644 in fluid communication with main shaft 602 via a passageway 646 formed in a head element 650. Head element 650 is fixed to main shaft 602 at an end thereof opposite the end at which anchor balloon 640 is located.

Disposed adjacent the end of main shaft 602 in fluid communication with peripheral balloon inflation location 622, exterior of an outer wall 652 thereof, is a peripheral balloon 660. Peripheral balloon 660 is selectably inflated, as shown in Figs. 10A - 10D, via second lumen 606, via a stopcock 662 and associated conduit 664 that communicate with second lumen 606 via a passageway 666 formed in head element 650.

Additionally, in accordance with a preferred embodiment of the present

invention, an electrical resistance heating element 680 is disposed interiorly of the anchor balloon 640. Preferably, the resistance heating element 680 is formed of a foil or a wire which is electrically coupled at opposite ends thereof to electrical conductors which extend through the main shaft 602. In the illustrated embodiment, a first conductor 682 is attached to a first end 684 of resistance heating element 680 and preferably extends through the first lumen 604, and a second conductor 686 is attached to a second end 688 of resistance heating element 680 and extends through the second lumen 606.

Electrical power is supplied to resistance heating element 680 via a switch 690, which couples first conductor 682 and second conductor 686 to a source of electrical power. Heating of resistance heating element 680 enhances hemostasis at the aperture in the artery.

Reference is now made to Figs. 9B – 9J, which illustrate various steps in a preferred mode of operation of the apparatus of Fig. 9A. Fig. 9B illustrates the hemostasis device 600 about to be inserted into an artery 700 via a conventional catheter introducer assembly 702, following completion of a catheterization procedure and withdrawal of a catheter (not shown) from the catheter introducer assembly 702. The catheter introducer assembly 702 conventionally includes a catheter introducer sheath 704.

Fig. 9C shows the hemostasis device 600 inserted into the catheter introducer assembly 702 such that the outer end of the main shaft 602 extends into the artery 700 well beyond the end of catheter introducer sheath 704. As shown with particularity in Fig. 9C, at this stage both anchor balloon 640 and peripheral balloon 660 are deflated, as seen clearly in Fig. 10A.

Reference is now made to Fig. 9D, which shows initial inflation of the anchor balloon 640, preferably by use of a syringe 720, communicating with first lumen 604 via passageway 646 extending through the interior of head element 650, stopcock 642 and associated conduit 644. The inflated anchor balloon 640 preferably has a cusp-type configuration as seen with particularity in Figs. 9D and 10B.

Following inflation of the anchor balloon 640, the catheter introducer assembly 702 and the hemostasis device 600 are both withdrawn, such that the catheter introducer sheath 704 is removed from artery 700 only when the anchor balloon 640

already engages the interior wall of artery 700 in sealing engagement with the aperture in the artery 700 through which the catheter introducer sheath 704 is withdrawn and through which the main shaft 602 presently extends. This stage is shown in Fig. 9E.

As seen in Figs. 9F and 10C, initial inflation of the peripheral balloon 660 is effected, preferably by use of a syringe 740 communicating with second lumen 606 via passageway 666 in head element 650, stopcock 662 and associated conduit 664.

Thereafter, as seen in Figs. 9G and 10D, the anchor balloon 640 is deflated, preferably by operation of syringe 720, communicating with first lumen 604 via passageway 646 in head element 650, stopcock 642 and associated conduit 644, and the peripheral balloon 660 remains fully inflated, which preferably causes the extreme end of the main shaft 602 to be withdrawn from the artery 700 to a location lying just outside the artery wall. As seen in Fig. 9G, peripheral balloon 660 is preferably designed to allow a limited volume of blood to collect outside of the artery wall after the anchor balloon 640 is deflated. This volume of blood is located in a region, indicated by reference numeral 750, delimited by the engagement of peripheral balloon 660 with the artery wall.

Preferably at this stage heating of the electrical resistance heating element 680 is effected, preferably by an operator closing switch 690, as shown in Fig. 9H. This heating preferably continues for less than five minutes.

Once acceptable hemostasis has occurred in region 750, the peripheral balloon 660 is deflated, as shown in Figs 9I and 10A, preferably by operation of syringe 740, communicating with second lumen 606 via passageway 666 in head element 650, stopcock 662 and associated conduit 664.

Thereafter, the hemostasis device 600 is entirely withdrawn from the patient, leaving a region 760 of hemostasis outside of artery 700, as shown in Fig. 9J.

Reference is now made to Figs. 11A, 11B, 11C, 11D, 11E, 11F, 11G, 11H, 11I and 11J, which are simplified illustrations of a hemostasis device constructed and operative in accordance with still another preferred embodiment of the present invention and various stages of its operation in a patient treatment context and to Figs. 12A, 12B, 12C and 12D, which are simplified illustrations of four different states of inflation of the hemostasis device.

Fig. 11A shows a hemostasis device 800 for producing hemostasis

following arterial catheterization, in accordance with yet another preferred embodiment of the present invention. The hemostasis device 800 is suitable for insertion via a conventional catheter introducer (not shown) following completion of catheterization and removal of the catheter from the catheter introducer.

In accordance with a preferred embodiment of the present invention, hemostasis device 800 comprises a main shaft 802, which has first and second lumens 804 and 806. First lumen 804 extends along the main shaft 802 to an anchor balloon inflation location 812. Second lumen 806 extends along the shaft 802 to a peripheral balloon inflation location 822.

Disposed at an end of main shaft 802 at anchor balloon inflation location 812 is an anchor balloon 840. Anchor balloon 840 is selectably inflated, as shown in Figs 12A - 12D, via a stopcock 842 and associated conduit 844 in fluid communication with main shaft 802 via a passageway 846 formed in a head element 850. Head element 850 is fixed to main shaft 802 at an end thereof opposite the end at which anchor balloon 840 is located.

Disposed adjacent the end of main shaft 802 in fluid communication with peripheral balloon inflation location 822, exterior of an outer wall 852 thereof, is a peripheral balloon 860. Peripheral balloon 860 is selectably inflated, as shown in Figs. 12A - 12D, via second lumen 806, via a stopcock 862 and associated conduit 864 that communicate with second lumen 806 via a passageway 866 formed in head element 850.

Additionally, in accordance with a preferred embodiment of the present invention, a pair of mutually spaced electrodes 880 is disposed interiorly of the anchor balloon 840. Alternatively, electrodes 880 are disposed exteriorly of anchor balloon 840. Preferably, the electrodes 880 are each formed to have a configuration of a ball or knob and are each electrically coupled to a corresponding electrical conductor which extend through the main shaft 802. In the illustrated embodiment, a first conductor 882, which preferably extends through the first lumen 804, is attached to a first electrode 880 and a second conductor 884 is attached to a second electrode 880 and extends through the second lumen 806.

Electrical power is supplied to electrodes 880 via a switch, which couples first conductor 882 and second conductor 884 to an RF power source 890. Heating of

electrodes 880 enhances hemostasis at the aperture in the artery.

Alternatively, a greater or lesser number of electrodes 880 may be employed. If only a single electrode 880 is provided, a suitable reference electrode (not shown) is preferably associated with a patient's body, such as underlying the patient.

Reference is now made to Figs. 11B – 11J, which illustrate various steps in a preferred mode of operation of the apparatus of Fig. 11A. Fig. 11B illustrates the hemostasis device 800 about to be inserted into an artery 900 via a conventional catheter introducer assembly 902, following completion of a catheterization procedure and withdrawal of a catheter (not shown) from the catheter introducer assembly 902. The catheter introducer assembly 902 conventionally includes a catheter introducer sheath 904.

Fig. 11C shows the hemostasis device 800 inserted into the catheter introducer assembly 902 such that the outer end of the main shaft 802 extends into the artery 900 well beyond the end of catheter introducer sheath 904. As shown with particularity in Fig. 11C, at this stage both anchor balloon 840 and peripheral balloon 860 are deflated, as seen clearly in Fig. 12A.

Reference is now made to Fig. 11D, which shows initial inflation of the anchor balloon 840, preferably by use of a syringe 920, communicating with first lumen 804 via passageway 846 extending through the interior of head element 850, stopcock 842 and associated conduit 844. The inflated anchor balloon 840 preferably has a cusp-type configuration as seen with particularity in Figs. 11D and 12B.

Following inflation of the anchor balloon 840, the catheter introducer assembly 902 and the hemostasis device 800 are both withdrawn, such that the catheter introducer sheath 904 is removed from artery 900 only when the anchor balloon 840 already engages the interior wall of artery 900 in sealing engagement with the aperture in the artery 900 through which the catheter introducer sheath 904 is withdrawn and through which the main shaft 802 presently extends. This stage is shown in Fig. 11E.

As seen in Figs. 11F and 12C, initial inflation of the peripheral balloon 860 is effected, preferably by use of a syringe 940 communicating with second lumen 806 via passageway 866 in head element 850, stopcock 862 and associated conduit 864.

Thereafter, as seen in Figs. 11G and 12D, the anchor balloon 840 is deflated, preferably by operation of syringe 920, communicating with first lumen 804

via passageway 846 in head element 850, stopcock 842 and associated conduit 844, and the peripheral balloon 860 remains fully inflated, which preferably causes the extreme end of the main shaft 802 to be withdrawn from the artery 900 to a location lying just outside the artery wall. As seen in Fig. 11G, peripheral balloon 860 is preferably designed to allow a limited volume of blood to collect outside of the artery wall after the anchor balloon 840 is deflated. This volume of blood is located in a region, indicated by reference numeral 950, delimited by the engagement of peripheral balloon 860 with the artery wall.

Preferably, at this stage, heating of the electrode or electrodes 880 is effected, preferably by an operator closing the switch coupling the first conductor 882 and the second conductor 884 to RF power source 890, as seen in Fig. 11H. This heating preferably continues for less than five minutes.

Once acceptable hemostasis has occurred in region 950, the peripheral balloon 860 is deflated, as shown in Figs 11I and 12A, preferably by operation of syringe 940, communicating with second lumen 806 via passageway 866 in head element 850, stopcock 862 and associated conduit 864.

Thereafter, the hemostasis device 800 is entirely withdrawn from the patient, leaving a region 960 of hemostasis outside of artery 900, as shown in Fig. 11J.

Reference is now made to Figs. 13A, 13B, 13C, 13D, 13E, 13F, 13G, 13H, 13I and 13J, which are simplified illustrations of a hemostasis device constructed and operative in accordance with still another preferred embodiment of the present invention and various stages of its operation in a patient treatment context and to Figs. 14A, 14B, 14C and 14D, which are simplified illustrations of four different states of inflation of the hemostasis device.

Fig. 13A shows a hemostasis device 1000 for producing hemostasis following arterial catheterization, in accordance with yet another preferred embodiment of the present invention. The hemostasis device 1000 is suitable for insertion via a conventional catheter introducer (not shown) following completion of catheterization and removal of the catheter from the catheter introducer.

In accordance with a preferred embodiment of the present invention, hemostasis device 1000 comprises a main shaft 1002, which has first and second lumens 1004 and 1006. First lumen 1004 extends along the main shaft 1002 to an anchor

balloon inflation location 1012. Second lumen 1006 extends along the shaft 1002 to a peripheral balloon inflation location 1022.

Disposed at an end of main shaft 1002 at anchor balloon inflation location 1012 is an anchor balloon 1040. Anchor balloon 1040 is selectably inflated, as shown in Figs 14A - 14D, via a stopcock 1042 and associated conduit 1044 in fluid communication with main shaft 1002 via a passageway 1046 formed in a head element 1050. Head element 1050 is fixed to main shaft 1002 at an end thereof opposite the end at which anchor balloon 1040 is located.

Disposed adjacent the end of main shaft 1002 in fluid communication with peripheral balloon inflation location 1022, exterior of an outer wall 1052 thereof, is a peripheral balloon 1060. Peripheral balloon 1060 is selectably inflated, as shown in Figs. 14A - 14D, via second lumen 1006, via a stopcock 1062 and associated conduit 1064 that communicate with second lumen 1006 via a passageway 1066 formed in head element 1050.

In accordance with a preferred embodiment of the present invention a coagulant agent supply conduit 1070 extends through the first lumen 1004 and through a bore 1072 formed along the length of head element 1050. Coagulant agent supply conduit 1070 communicates at one end thereof with a volume defined by inflation of the peripheral balloon 1060, between the balloon 1060 and the outer surface of an adjacent artery (not shown). At its opposite end, conduit 1070 communicates with a supply of coagulant agent (not shown) via a stopcock 1074 and associated conduit 1076.

Additionally, in accordance with a preferred embodiment of the present invention, an electrical resistance heating element 1080 is disposed interiorly of the anchor balloon 1040. Preferably, the resistance heating element 1080 is formed of a foil or a wire which is electrically coupled at opposite ends thereof to electrical conductors which extend through the main shaft 1002. In the illustrated embodiment, a first conductor, attached to a first end 1084 of resistance heating element 1080, is defined by or on the coagulant agent supply conduit 1070, which preferably extends through the first lumen 1004, and a second conductor 1086 is attached to a second end 1088 of resistance heating element 1080 and extends through the second lumen 1006.

Electrical power is supplied to resistance heating element 1080 via a switch 1090, which couples the first conductor, defined by conduit 1070, and second

conductor 1086 to a source of electrical power. Heating of resistance heating element 1080 enhances hemostasis at the aperture in the artery. The operation of the resistance heating element 1080 as aforesaid is advantageously combined in this embodiment with the provision of a coagulation agent as described hereinabove.

Reference is now made to Figs. 13B – 13J, which illustrate various steps in a preferred mode of operation of the apparatus of Fig. 13A. Fig. 13B illustrates the hemostasis device 1000 about to be inserted into an artery 1100 via a conventional catheter introducer assembly 1102, following completion of a catheterization procedure and withdrawal of a catheter (not shown) from the catheter introducer assembly 1102. The catheter introducer assembly 1102 conventionally includes a catheter introducer sheath 1104.

Fig. 13C shows the hemostasis device 1000 inserted into the catheter introducer assembly 1102 such that the outer end of the main shaft 1002 extends into the artery 1100 well beyond the end of catheter introducer sheath 1104. As shown with particularity in Fig. 13C, at this stage both anchor balloon 1040 and peripheral balloon 1060 are deflated, as seen clearly in Fig. 14A.

Reference is now made to Fig. 13D, which shows initial inflation of the anchor balloon 1040, preferably by use of a syringe 1120, communicating with first lumen 1004 via passageway 1046 extending through the interior of head element 1050, stopcock 1042 and associated conduit 1044. The inflated anchor balloon 1040 preferably has a cusp-type configuration as seen with particularity in Figs. 13D and 14B.

Following inflation of the anchor balloon 1040, the catheter introducer assembly 1102 and the hemostasis device 1000 are both withdrawn, such that the catheter introducer sheath 1104 is removed from artery 1100 only when the anchor balloon 1040 already engages the interior wall of artery 1100 in sealing engagement with the aperture in the artery 1100 through which the catheter introducer sheath 1104 is withdrawn and through which the main shaft 1002 presently extends. This stage is shown in Fig. 13E.

As seen in Figs. 13F and 14C, initial inflation of the peripheral balloon 1060 is effected, preferably by use of a syringe 1140 communicating with second lumen 1006 via passageway 1066 in head element 1050, stopcock 1062 and associated conduit

1064.

Thereafter, as seen in Figs. 13G and 14D, the anchor balloon 1040 is deflated, preferably by operation of syringe 1120, communicating with first lumen 1004 via passageway 1046 in head element 1050, stopcock 1042 and associated conduit 1044, and the peripheral balloon 1060 remains fully inflated, which preferably causes the extreme end of the main shaft 1002 to be withdrawn from the artery 1100 to a location lying just outside the artery wall. As seen in Fig. 13G, peripheral balloon 1060 is preferably designed to allow a limited volume of blood to collect outside of the artery wall after the anchor balloon 1040 is deflated. This volume of blood is located in a region, indicated by reference numeral 1150, delimited by the engagement of peripheral balloon 1060 with the artery wall.

At this stage, a coagulant agent is preferably supplied to the volume of blood at region 1150, between the balloon 1060 and the outer surface of artery 1100. The coagulant agent is supplied to region 1150 by conduit 1070 from a supply of coagulant agent 1152 via stopcock 1074 and associated conduit 1076, as shown in Fig. 13H.

Preferably also at this stage, heating of the electrical resistance heating element 1080 is effected, preferably by an operator closing switch 1090. This heating preferably continues for less than five minutes.

Once acceptable hemostasis has occurred in region 1150, the peripheral balloon 1060 is deflated, as shown in Figs 13I and 14A, preferably by operation of syringe 1140, communicating with second lumen 1006 via passageway 1066 in head element 1050, stopcock 1062 and associated conduit 1064.

Thereafter, the hemostasis device 1000 is entirely withdrawn from the patient, leaving a region 1160 of hemostasis outside of artery 1100, as shown in Fig. 13J.

Reference is now made to Figs. 15A, 15B, 15C, 15D, 15E, 15F, 15G, 15H, 15I and 15J, which are simplified illustrations of a hemostasis device constructed and operative in accordance with still another preferred embodiment of the present invention and various stages of its operation in a patient treatment context and to Figs. 16A, 16B, 16C and 16D, which are simplified illustrations of four different states of inflation of the hemostasis device.

Fig. 15A shows a hemostasis device 1200 for producing hemostasis following arterial catheterization, in accordance with yet another preferred embodiment of the present invention. The hemostasis device 1200 is suitable for insertion via a conventional catheter introducer (not shown) following completion of catheterization and removal of the catheter from the catheter introducer.

In accordance with a preferred embodiment of the present invention, hemostasis device 1200 comprises a main shaft 1202, which has first and second lumens 1204 and 1206. First lumen 1204 extends along the main shaft 1202 to an anchor balloon inflation location 1212. Second lumen 1206 extends along the shaft 1202 to a peripheral balloon inflation location 1222.

Disposed at an end of main shaft 1202 at anchor balloon inflation location 1212 is an anchor balloon 1240. Anchor balloon 1240 is selectably inflated, as shown in Figs 16A - 16D, via a stopcock 1242 and associated conduit 1244 in fluid communication with main shaft 1202 via a passageway 1246 formed in a head element 1250. Head element 1250 is fixed to main shaft 1202 at an end thereof opposite the end at which anchor balloon 1240 is located.

Disposed adjacent the end of main shaft 1202 in fluid communication with peripheral balloon inflation location 1222, exterior of an outer wall 1252 thereof, is a peripheral balloon 1260. Peripheral balloon 1260 is selectably inflated, as shown in Figs. 16A - 16D, via second lumen 1206, via a stopcock 1262 and associated conduit 1264 that communicate with second lumen 1206 via a passageway 1266 formed in head element 1250.

In accordance with a preferred embodiment of the present invention a coagulant agent supply conduit 1270 extends through the first lumen 1204 and through a bore 1272 formed in head element 1250. Coagulant agent supply conduit 1270 communicates at one end thereof, via a coagulant agent aperture 1273, with a volume defined by inflation of the peripheral balloon 1260, between the balloon 1260 and the outer surface of an adjacent artery (not shown). At its opposite end, conduit 1270 communicates with a supply of coagulant agent (not shown) via a stopcock 1274 and associated conduit 1276. Coagulant agent aperture 1273 is clearly shown in Figs. 16A-16D.

Additionally, in accordance with a preferred embodiment of the present

invention, a pair of mutually spaced electrodes 1280 is disposed interiorly of the anchor balloon 1240. Alternatively, electrodes 1280 are disposed exteriorly of anchor balloon 1240. Preferably, the electrodes 1280 are each formed to have a configuration of a ball or knob and are each electrically coupled to a corresponding electrical conductor which extend through the main shaft 1202. In the illustrated embodiment, a first conductor, attached to a first electrode 1280, is defined by or on the coagulant agent supply conduit 1270, which preferably extends through the first lumen 1204, and a second conductor 1286 is attached to a second electrode 1280 and extends through the second lumen 1206.

Electrical power is supplied to electrodes 1280 via a switch, which couples the first conductor and the second conductor 1286 to an RF power source 1290. Heating of electrodes 1280 enhances hemostasis at the aperture in the artery. The operation of the electrodes 1280 as aforesaid is advantageously combined in this embodiment with the provision of a coagulation agent as described hereinabove.

Alternatively, a greater or lesser number of electrodes 1280 may be employed. If only a single electrode 1280 is provided, a suitable reference electrode (not shown) is preferably associated with a patient's body, such as underlying the patient.

Reference is now made to Figs. 15B – 15J, which illustrate various steps in a preferred mode of operation of the apparatus of Fig. 15A. Fig. 15B illustrates the hemostasis device 1200 about to be inserted into an artery 1300 via a conventional catheter introducer assembly 1302, following completion of a catheterization procedure and withdrawal of a catheter (not shown) from the catheter introducer assembly 1302. The catheter introducer assembly 1302 conventionally includes a catheter introducer sheath 1304.

Fig. 15C shows the hemostasis device 1200 inserted into the catheter introducer assembly 1302 such that the outer end of the main shaft 1202 extends into the artery 1300 well beyond the end of catheter introducer sheath 1304. As shown with particularity in Fig. 15C, at this stage both anchor balloon 1240 and peripheral balloon 1260 are deflated, as seen clearly in Fig. 16A.

Reference is now made to Fig. 15D, which shows initial inflation of the anchor balloon 1240, preferably by use of a syringe 1320, communicating with first lumen 1204 via passageway 1246 extending through the interior of head element 1250,

stopcock 1242 and associated conduit 1244. The inflated anchor balloon 1240 preferably has a cusp-type configuration as seen with particularity in Figs. 15D and 16B.

Following inflation of the anchor balloon 1240, the catheter introducer assembly 1302 and the hemostasis device 1200 are both withdrawn, such that the catheter introducer sheath 1304 is removed from artery 1300 only when the anchor balloon 1240 already engages the interior wall of artery 1300 in sealing engagement with the aperture in the artery 1300 through which the catheter introducer sheath 1304 is withdrawn and through which the main shaft 1202 presently extends. This stage is shown in Fig. 15E.

As seen in Figs. 15F and 16C, initial inflation of the peripheral balloon 1260 is effected, preferably by use of a syringe 1340 communicating with second lumen 1206 via passageway 1266 in head element 1250, stopcock 1262 and associated conduit 1264.

Thereafter, as seen in Figs. 15G and 16D, the anchor balloon 1240 is deflated, preferably by operation of syringe 1320, communicating with first lumen 1204 via passageway 1246 in head element 1250, stopcock 1242 and associated conduit 1244, and the peripheral balloon 1260 remains fully inflated, which preferably causes the extreme end of the main shaft 1202 to be withdrawn from the artery 1300 to a location lying just outside the artery wall. As seen in Fig. 15G, peripheral balloon 1260 is preferably designed to allow a limited volume of blood to collect outside of the artery wall after the anchor balloon 1240 is deflated. This volume of blood is located in a region, indicated by reference numeral 1350, delimited by the engagement of peripheral balloon 1260 with the artery wall.

At this stage, a coagulant agent is preferably supplied to the volume of blood at region 1350, between the balloon 1260 and the outer surface of artery 1300. The coagulant agent is supplied to region 1350 by conduit 1270, via coagulant agent aperture 1273 from a supply of coagulant agent 1352 via stopcock 1274 and associated conduit 1276, as shown in Fig. 15H.

Preferably, also at this stage, heating of the electrode or electrodes 1280 is effected, preferably by an operator closing the switch coupling the first conductor and the second conductor 1286 to RF power source 1290, as seen in Fig. 15H. This heating

preferably continues for less than five minutes.

Once acceptable hemostasis has occurred in region 1350, the peripheral balloon 1260 is deflated, as shown in Figs 15I and 16A, preferably by operation of syringe 1340, communicating with second lumen 1206 via passageway 1266 in head element 1250, stopcock 1262 and associated conduit 1264.

Thereafter, the hemostasis device 1200 is entirely withdrawn from the patient, leaving a region 1360 of hemostasis outside of artery 1300, as shown in Fig. 15J.

It will be appreciated by persons skilled in the art that the present invention is not limited by what has been particularly shown and described hereinabove. Rather the scope of the present invention includes both combinations and subcombinations of the various features described hereinabove and shown in the drawings as well as modifications and further developments thereof which would occur to a person of ordinary skill in the art upon reading the foregoing description and which are not in the prior art.

CLAIMS

1. A hemostasis device comprising:

a resistance heating element for accelerating hemostasis;

a blood resistance sensor; and

a blood resistance indicator, operative to provide an indication of the resistance at said resistance sensor of blood undergoing hemostasis.

2. A hemostasis device according to claim 1 and also comprising a power supply connected to said resistance heating element, said resistance sensor and said resistance indicator.

3. A hemostasis device according to claim 2 and wherein said power supply is operative to supply a relatively high level current to said resistance heating element.

4. A hemostasis device according to either of claims 2 and 3 and wherein said power supply is operative to supply a relatively low level current to said resistance sensor.

5. A method for accelerating hemostasis of an artery of a patient having a puncture after arterial catheterization, the method comprising the steps of:

following arterial catheterization, introducing a hemostasis device, such that a forward end of said hemostasis device lies exterior of the artery adjacent said puncture;

accelerating hemostasis by heating tissue in the vicinity of said puncture, thereby shortening the time required for hemostasis; and

following hemostasis, removing said hemostasis device from the patient.

6. A method according to claim 5 and also comprising inserting a catheter introducer into said artery prior to said arterial catheterization and wherein following said arterial catheterization, said hemostasis device is introduced through said catheter introducer.

7. A method according to any of claims 5 - 6 and also comprising measuring the conductivity of blood in the vicinity of said puncture during hemostasis.

8. A method for monitoring the progress of hemostasis of an artery of a patient having a puncture after arterial catheterization, the method comprising the steps of:

following arterial catheterization, introducing a hemostasis device, such that a forward end of said hemostasis device lies exterior of the artery adjacent said puncture;

during hemostasis, measuring the heat conductivity of blood in the vicinity of said puncture, thereby to provide an output indication of the progress of hemostasis; and

following hemostasis, removing said hemostasis device from the patient.

9. A method according to claim 8 and also comprising the step of inserting into an artery a catheter introducer prior to arterial catheterization and wherein following said arterial catheterization, said hemostasis device is introduced through said catheter introducer.

10. A method according to either of claim 8 or claim 9 and also comprising inflating a balloon to block said puncture, prior to said hemostasis.

11. A method according to claim 10 and also comprising deflating said balloon prior to removing said hemostasis device.

12. A hemostasis device comprising:

a main shaft;

at least one balloon mounted on said main shaft; and

at least one electrode, mounted on said main shaft and being operable to supply an electric current suitable for causing hemostasis.

13. A hemostasis device according to claim 12 and wherein said at least one balloon comprises:

at least one anchor balloon, disposed at an end of said main shaft; and

at least one peripheral balloon, disposed at a location along said main shaft exterior to a wall of said main shaft.

14. A hemostasis device according to claim 13 and wherein said at least one peripheral balloon and a wall of an artery are configured to delimit a region which is subject to hemostasis.

15. A hemostasis device according to any of claims 12 - 14 and also comprising an electrical power source and a control module.

16. A hemostasis device according to claim 15 and wherein said power source is an RF power supply.

17. A hemostasis device according to claim 16 and wherein said RF power supply is operative to supply electrical power at RF frequencies within a range of 0.1 - 10 watts at up to 25 volts.

18. A hemostasis device according to any of claims 15 - 17 and wherein said control module is operative to measure at least one of electrical current, blood resistance and blood temperature.

19. A hemostasis device according to any of claims 15 - 18 and wherein said control module is operative to adjust power supplied by said power source based on at least one measurement.

20. A hemostasis device according to any of claims 12 - 19 and wherein said at least one electrode comprises a pair of electrodes.

21. A method for producing hemostasis at an artery of a patient having a

puncture following arterial catheterization comprising:

introducing a hemostasis device comprising at least one electrode into the vicinity of said puncture;

supplying an electric current to said at least one electrode, thereby heating a volume of blood in the vicinity of said puncture, causing hemostasis; and

subsequently removing said hemostasis device from the patient.

22. A method according to claim 21 and wherein said introducing comprises introducing via a catheter introducer.

23. A method according to either of claims 21 and 22 and wherein said introducing also comprises inflating an anchor balloon attached to an end of said hemostasis device.

24. A method according to any of claims 21 - 23 and wherein said introducing comprises inflating a peripheral balloon.

25. A method according to claim 24 and wherein said removing said hemostasis device comprises deflating said peripheral balloon.

26. A method according to any of claims 21-25 and wherein said introducing comprises positioning said at least one electrode in close proximity to a volume of blood.

27. A method according to any of claims 21 - 26 and wherein said supplying comprises supplying electrical power at RF frequencies.

28. A method according to claim 27 and wherein said electrical power comprises electrical power in the range of 0.1 - 10 watts at up to 25 volts.

29. A method according to any of claims 21 - 28 and wherein said supplying also comprises adjusting said electric current based on a feedback measurement.

30. A hemostasis device comprising:

a main shaft;

at least one balloon mounted on said main shaft adjacent an end thereof; and

a hemostasis agent supply conduit operative to supply a hemostasis agent at a location at an end of said main shaft beyond said at least one balloon.

31. A hemostasis device according to claim 30 and also comprising at least one heating assembly operative to provide heating at said location.

32. A hemostasis device according to claim 31 and wherein said at least one heating assembly comprises at least one electrode disposed adjacent said location.

33. A hemostasis device according to claim 32 and wherein said at least one electrode is disposed interiorly of said at least one balloon.

34. A hemostasis device according to claim 32 and wherein said at least one electrode is disposed exteriorly of said at least one balloon.

35. A hemostasis device according to any of claims 31 - 33 and wherein said at least one heating assembly comprises an electrical resistive heating element.

36. A hemostasis device according to claim 35 and wherein said electrical resistive heating element is disposed within said at least one balloon.

37. A hemostasis device comprising:

a main shaft;

at least one balloon mounted on said main shaft adjacent an end thereof; and

at least one RF electrode located at a location at an end of said main shaft beyond said at least one balloon.

38. A hemostasis device according to claim 37 and also comprising a hemostasis agent supply conduit operative to supply a hemostasis agent at a location at an end of said main shaft beyond said at least one balloon.

39. A hemostasis device according to claim 37 and wherein said at least one RF electrode is disposed interiorly of said at least one balloon.

40. A hemostasis device according to claim 37 and wherein said at least one RF electrode is disposed exteriorly of said at least one balloon.

41. A hemostasis device comprising:

a main shaft;

at least one balloon mounted on said main shaft adjacent an end thereof; and

at least one resistive heating element located at a location at an end of said main shaft beyond said at least one balloon.

42. A hemostasis device according to claim 41 and also comprising a hemostasis agent supply conduit operative to supply a hemostasis agent at a location at an end of said main shaft beyond said at least one balloon.

43. A hemostasis device according to claim 42 and wherein said at least one resistance heating element is disposed interiorly of said at least one balloon.

44. A method for producing hemostasis at an artery of a patient having a puncture following arterial catheterization comprising:

introducing a hemostasis device including at least one balloon mounted adjacent an end of a shaft to a location in the vicinity of said puncture; and

supplying a hemostasis agent to said location at said end of said shaft beyond said at least one balloon.

45. A method according to claim 44 and also comprising providing heating at said location.

46. A method according to claim 45 and wherein said providing heating includes locating at least one electrode adjacent said location.

47. A method according to claim 46 and wherein said at least one electrode is disposed interiorly of said at least one balloon.

48. A method according to claim 46 and wherein said at least one electrode is disposed exteriorly of said at least one balloon.

49. A method according to any of claims 45 - 48 and wherein said providing heating comprises providing electrical resistive heating.

50. A method for producing hemostasis at an artery of a patient having a puncture following arterial catheterization comprising:

introducing a hemostasis device including at least one balloon mounted adjacent an end of a shaft to a location in the vicinity of said puncture; and

operating at least one RF electrode at said location at said end of said main shaft beyond said at least one balloon.

51. A method according to claim 50 and also comprising:

supplying a hemostasis agent to said location at said end of said shaft beyond said at least one balloon.

52. A method according to either of claims 50 and 51 and wherein said at least one RF electrode is disposed interiorly of said at least one balloon.

53. A method according to either of claims 50 and 51 and wherein said at least one RF electrode is disposed exteriorly of said at least one balloon.

54. A method for producing hemostasis at an artery of a patient having a puncture following arterial catheterization comprising:

introducing a hemostasis device including at least one balloon mounted adjacent an end of a shaft to a location in the vicinity of said puncture; and

operating at least one resistance heating element at said location at an end of said shaft beyond said at least one balloon.

55. A method according to claim 54 and also comprising:

supplying a hemostasis agent to said location at said end of said shaft beyond said at least one balloon.

56. A method according to either of claims 54 and 55 and wherein said at least one resistance heating element is disposed interiorly of said at least one balloon.

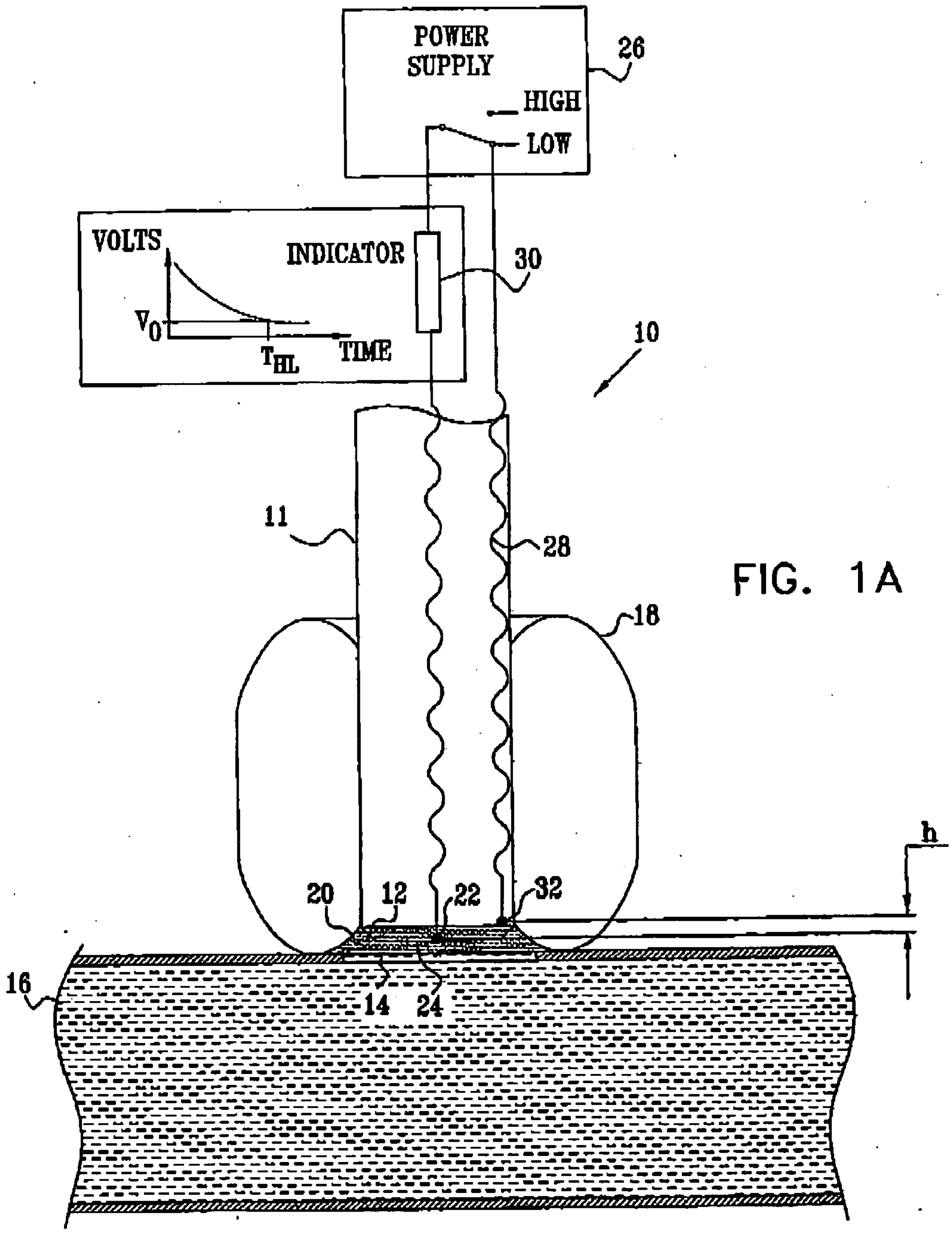
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FIG. 1A

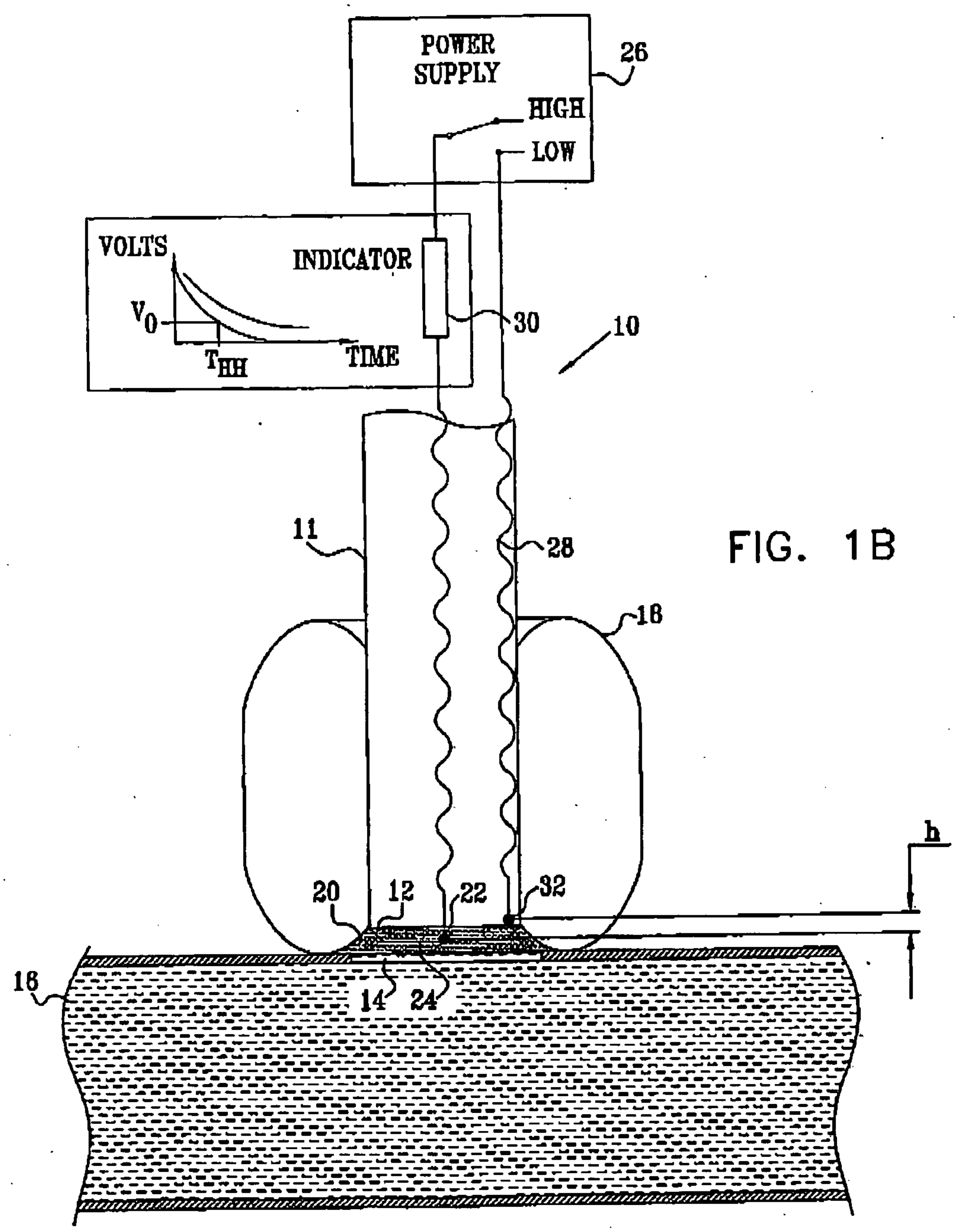
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FIG. 1B

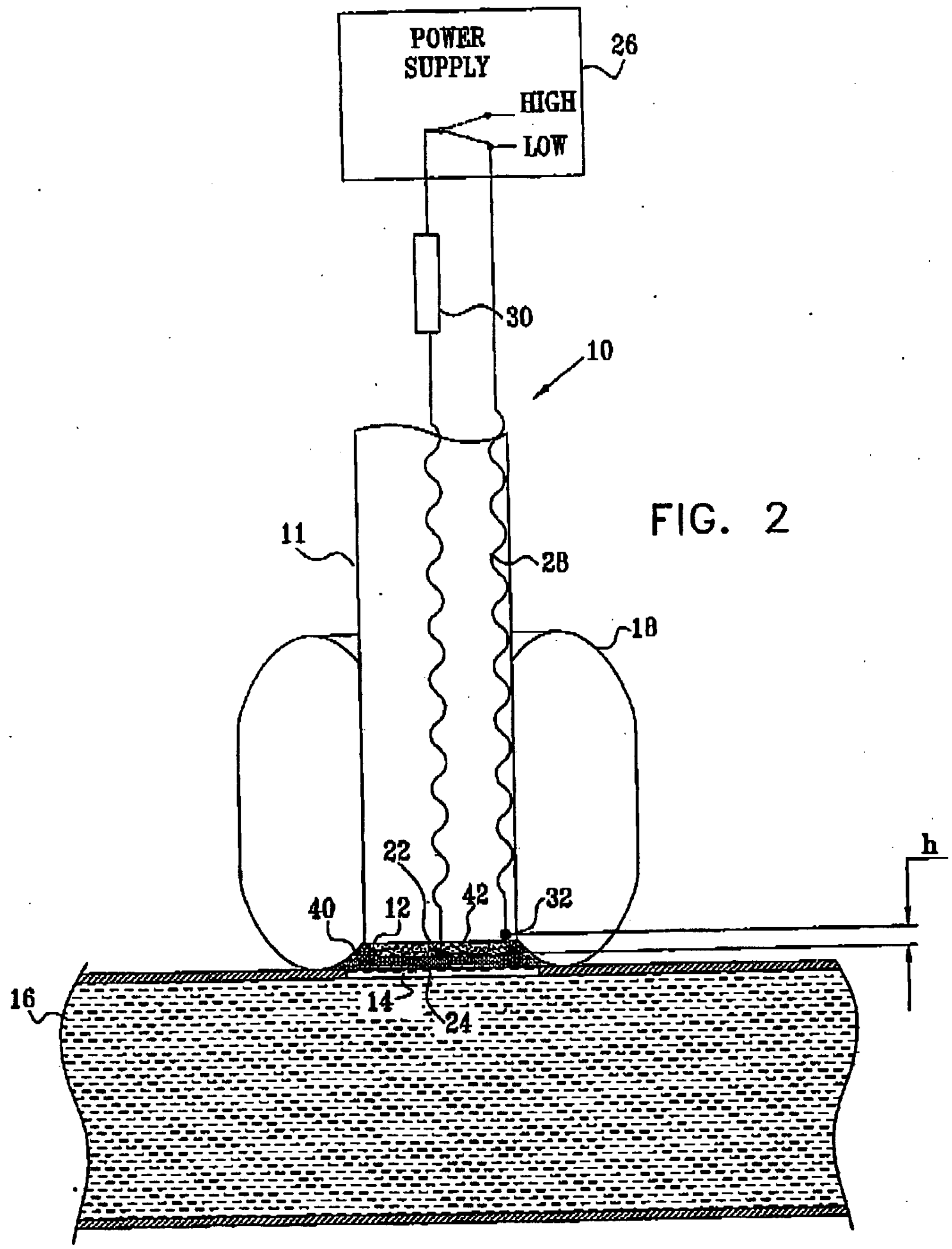


FIG. 2

FIG. 3A

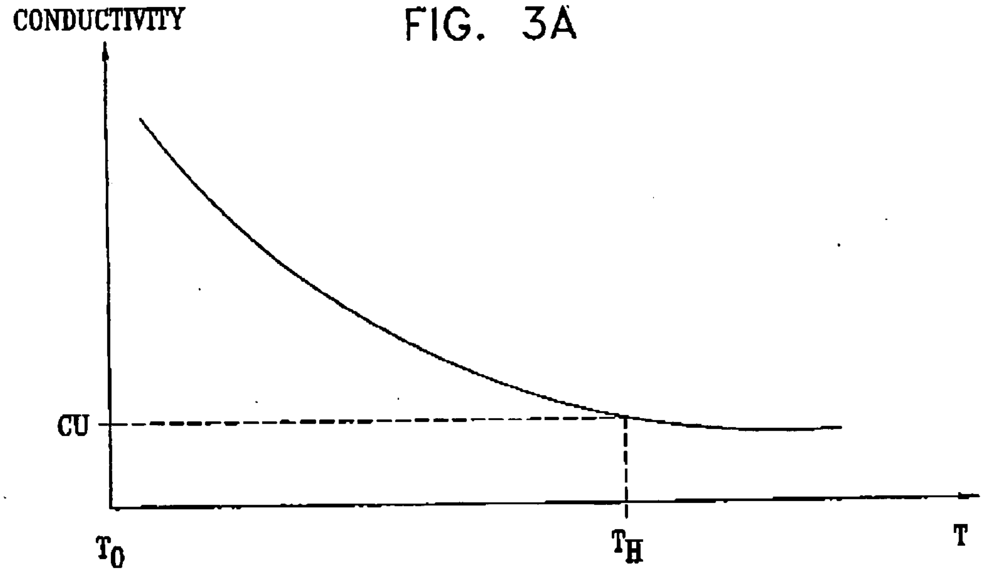
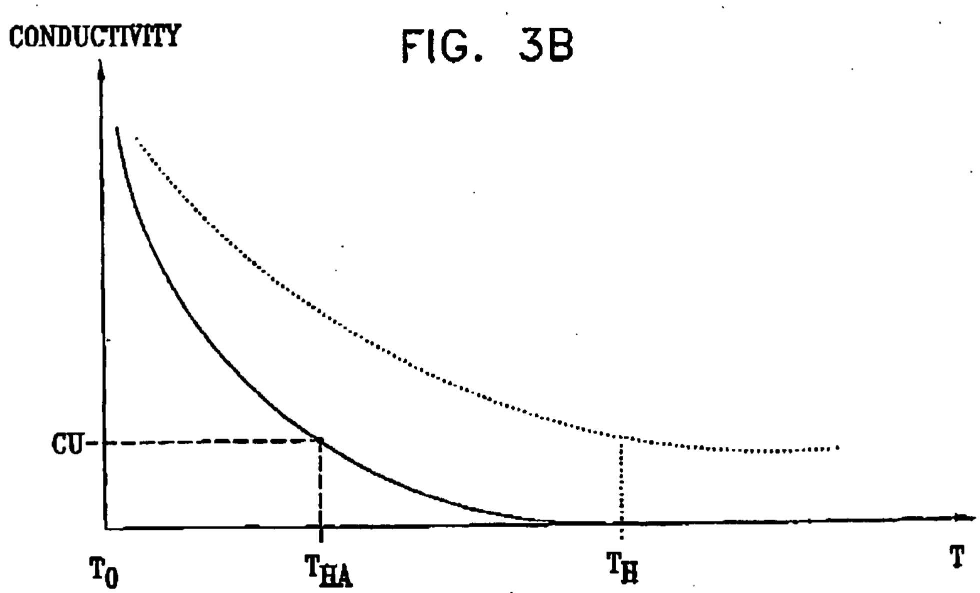


FIG. 3B



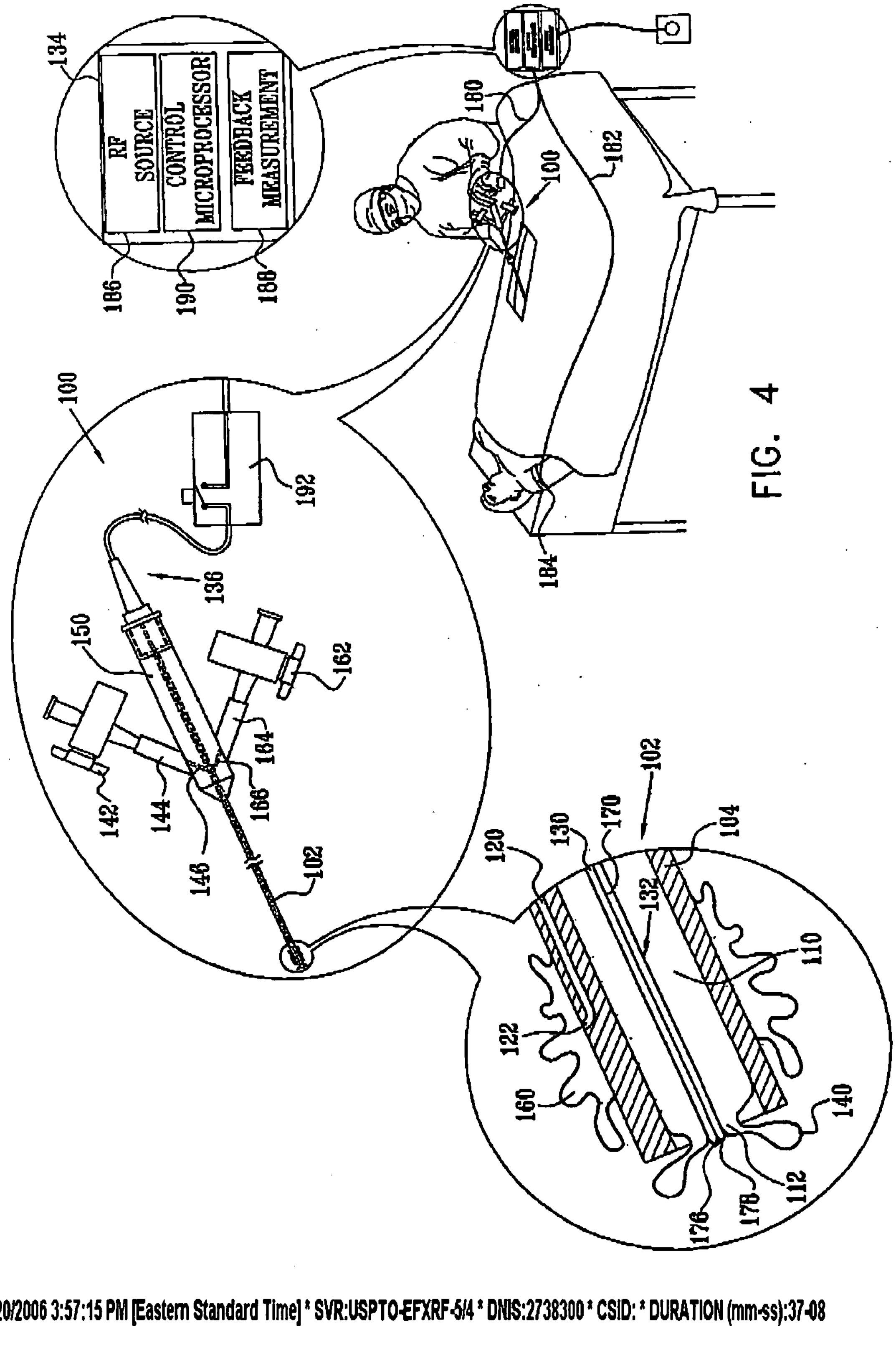


FIG. 4

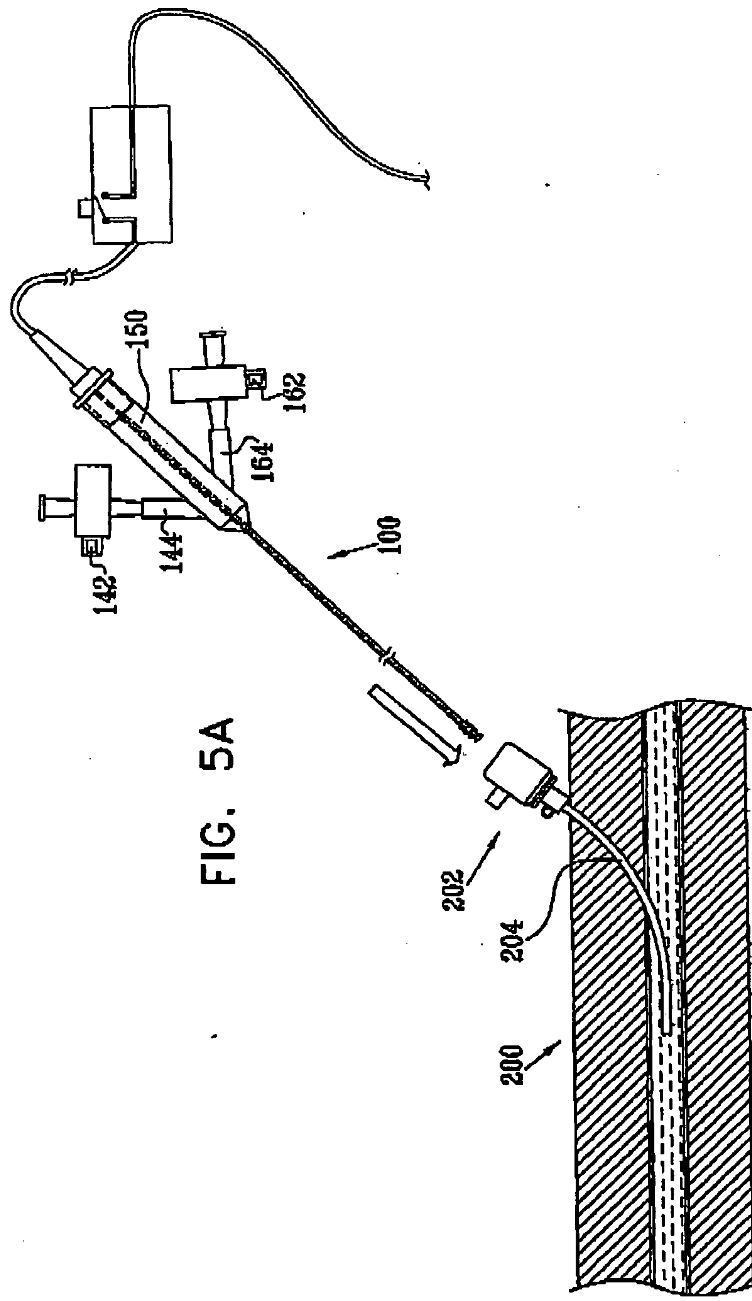
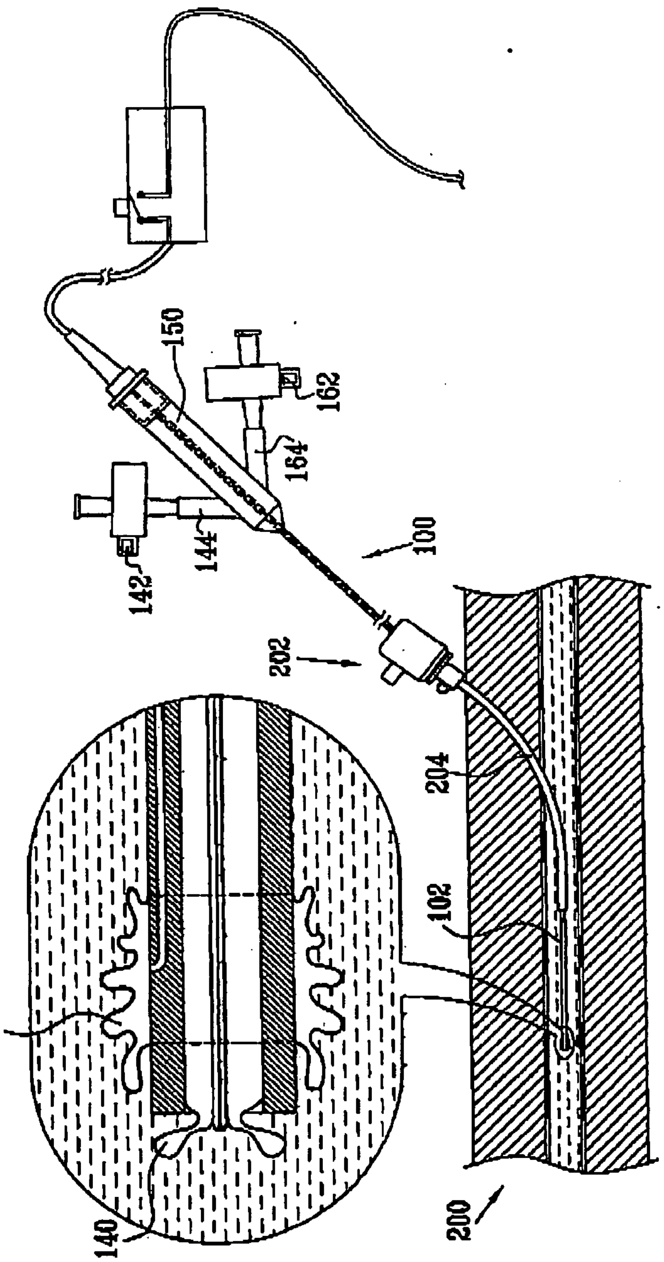


FIG. 5A

FIG. 5B



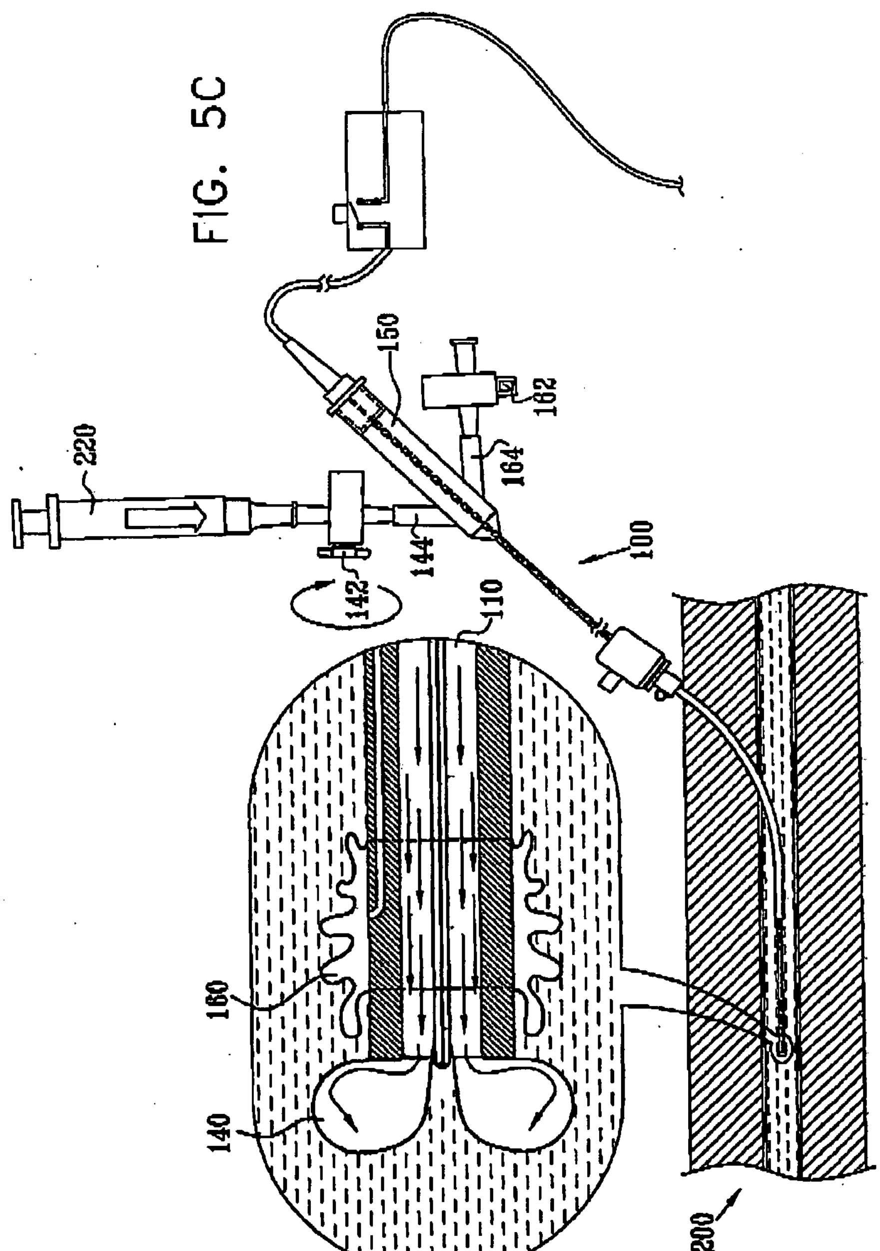


FIG. 5C

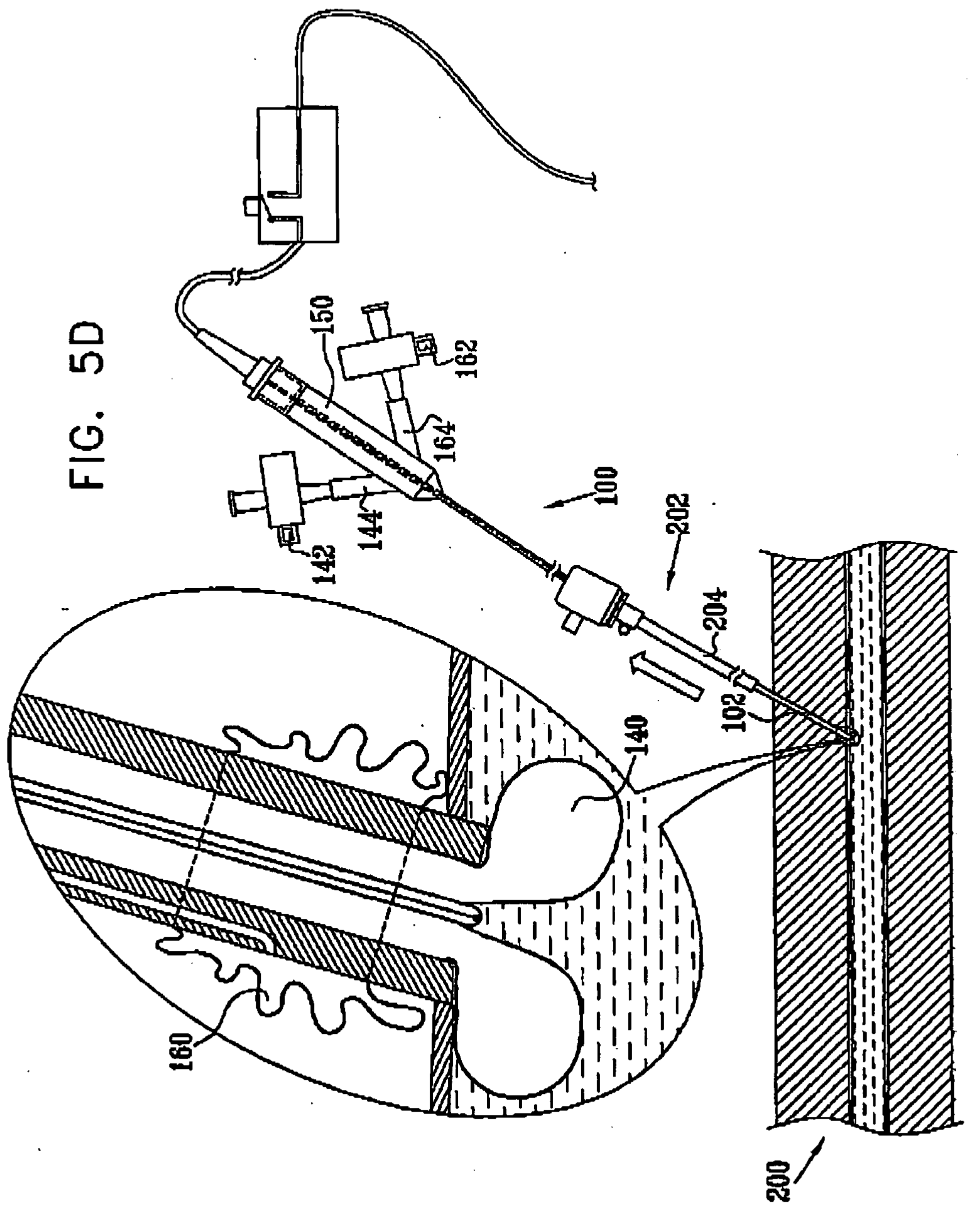


FIG. 5D

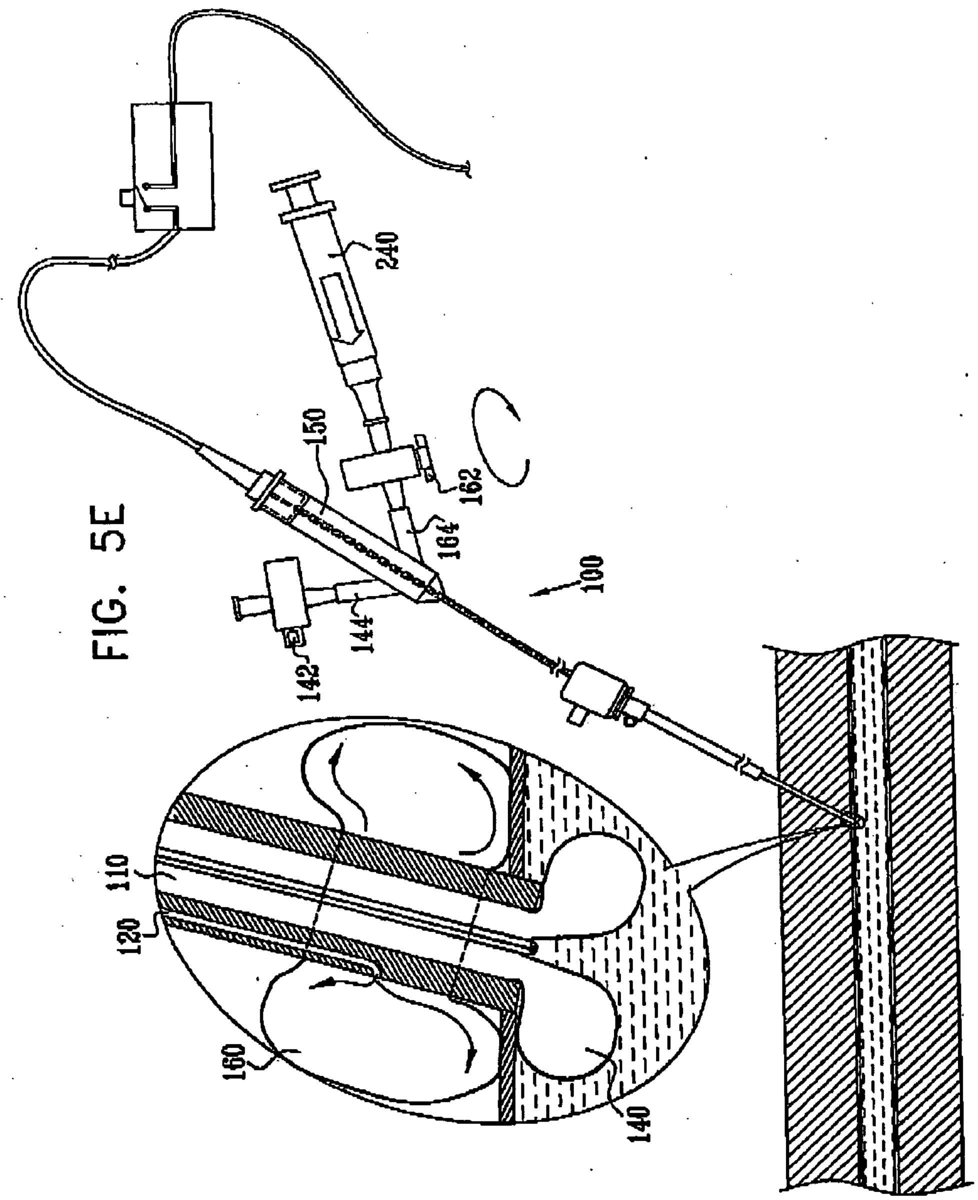


FIG. 5E

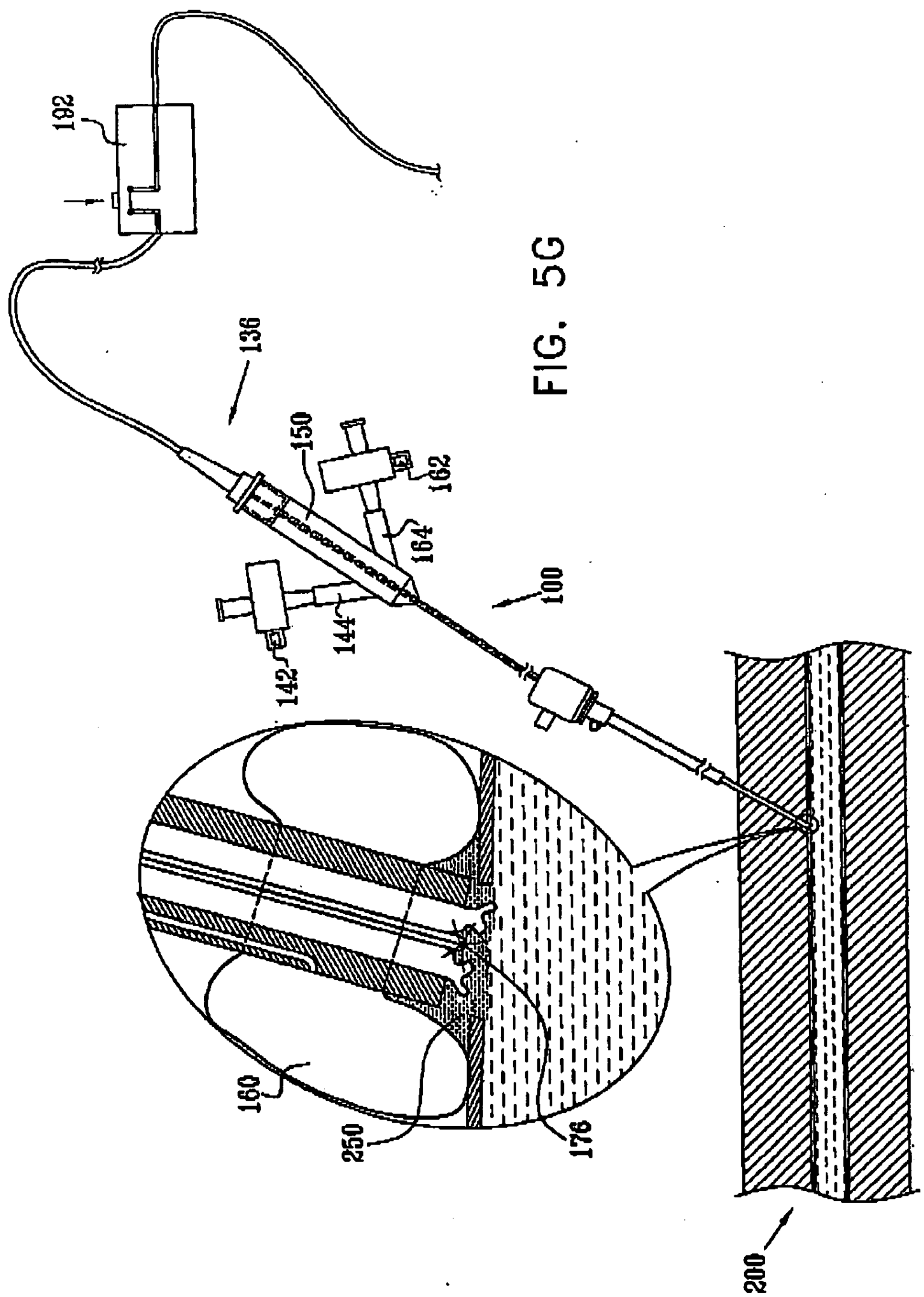


FIG. 5G

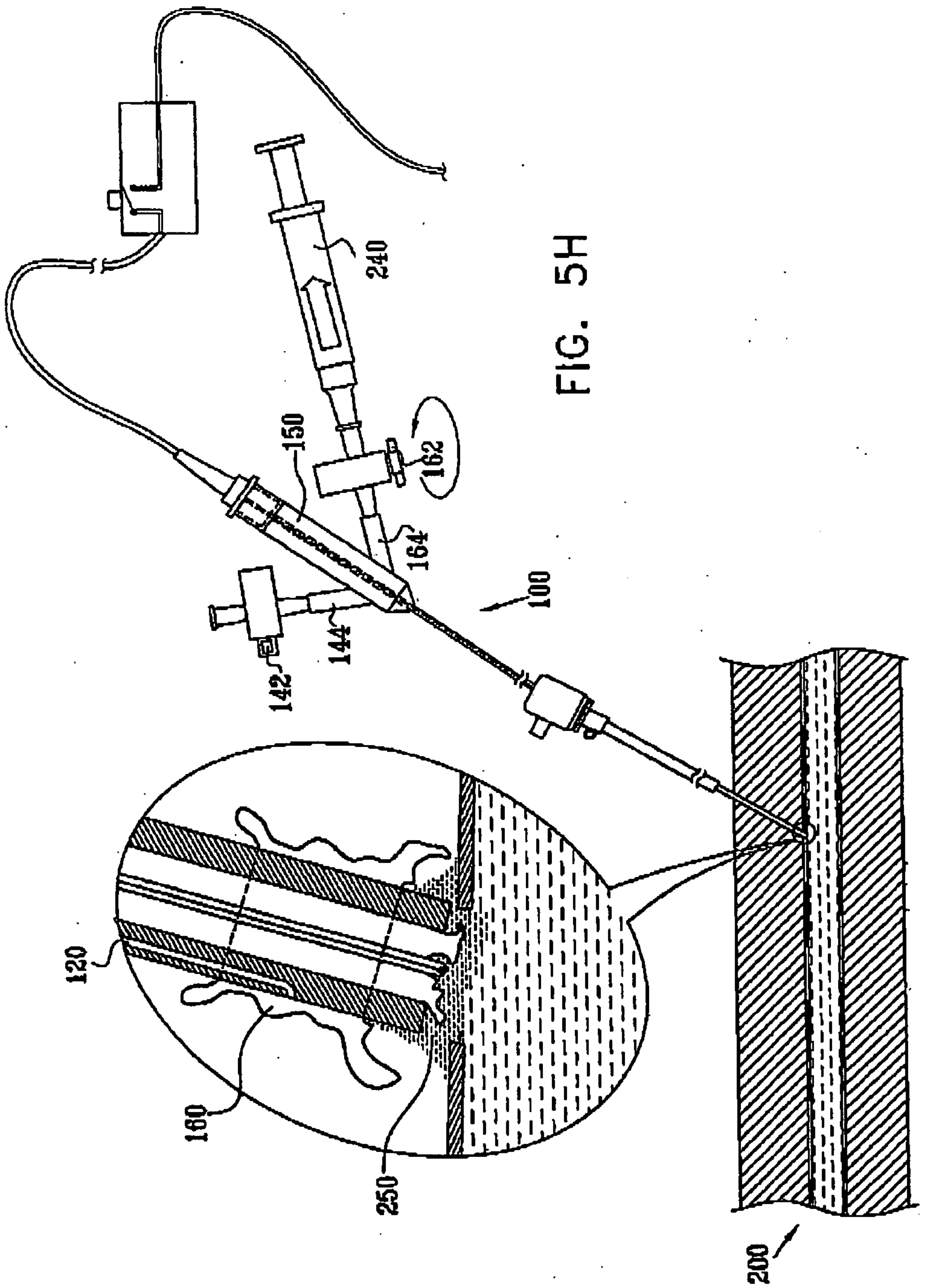


FIG. 5H

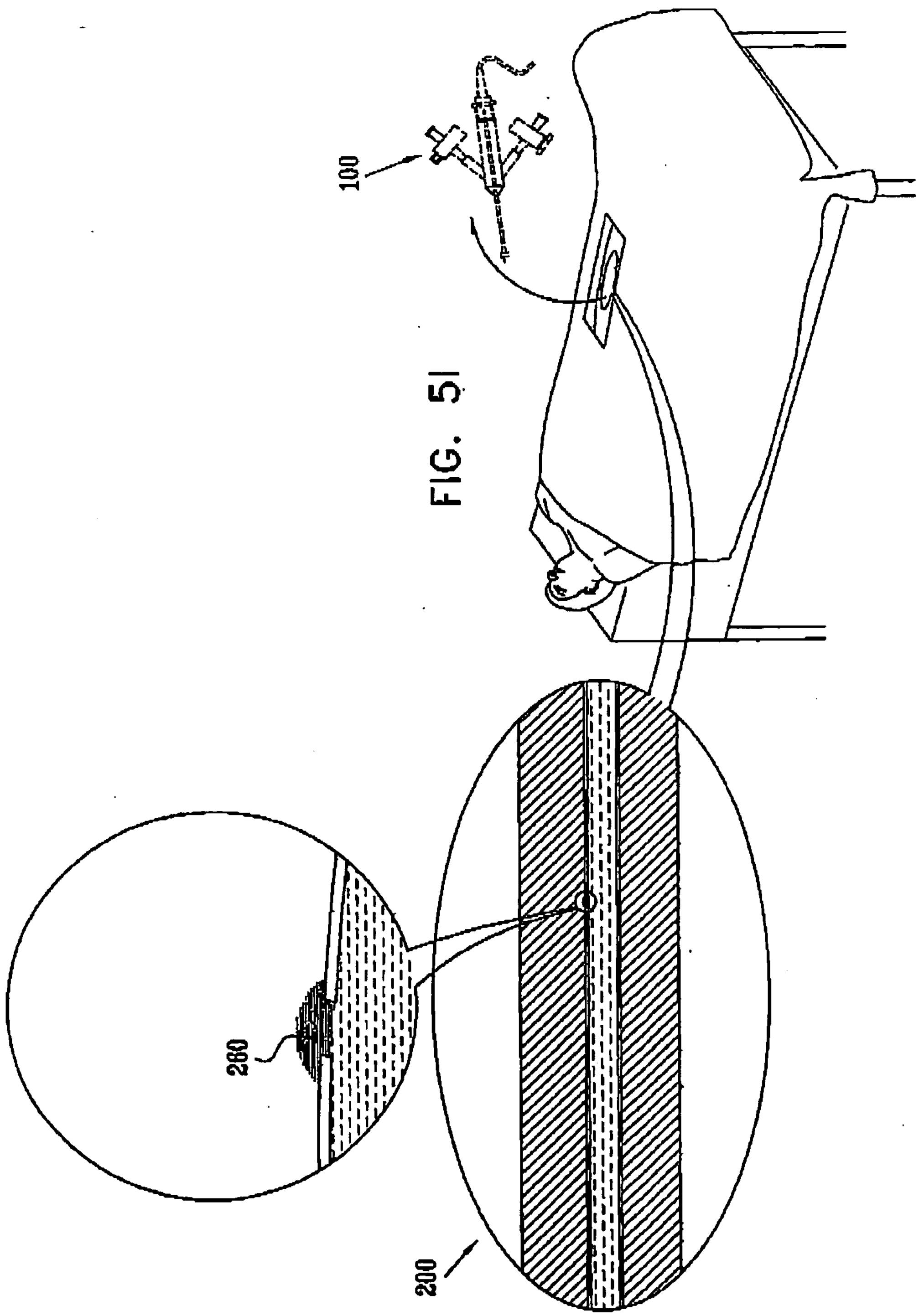


FIG. 5I

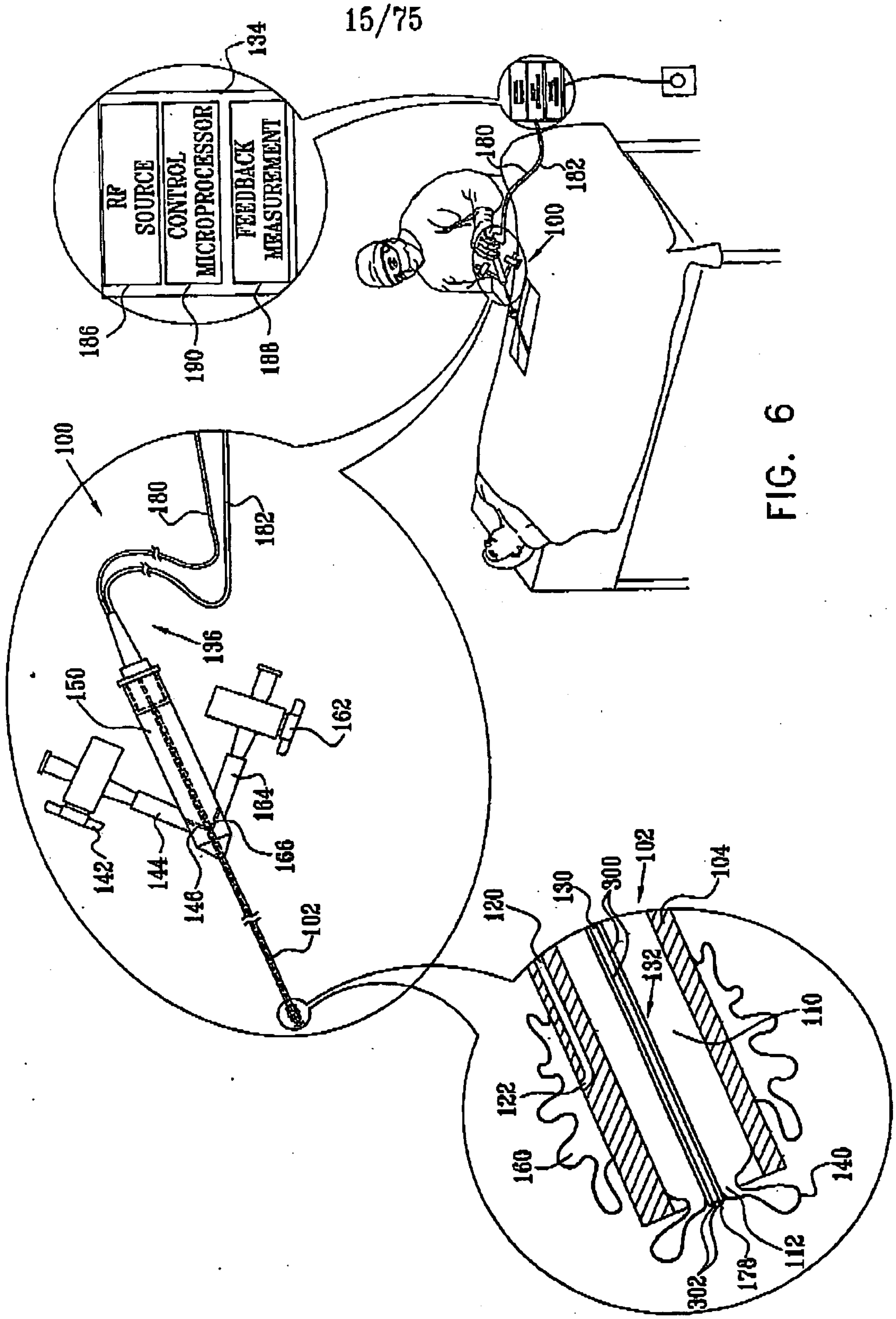

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FIG. 6

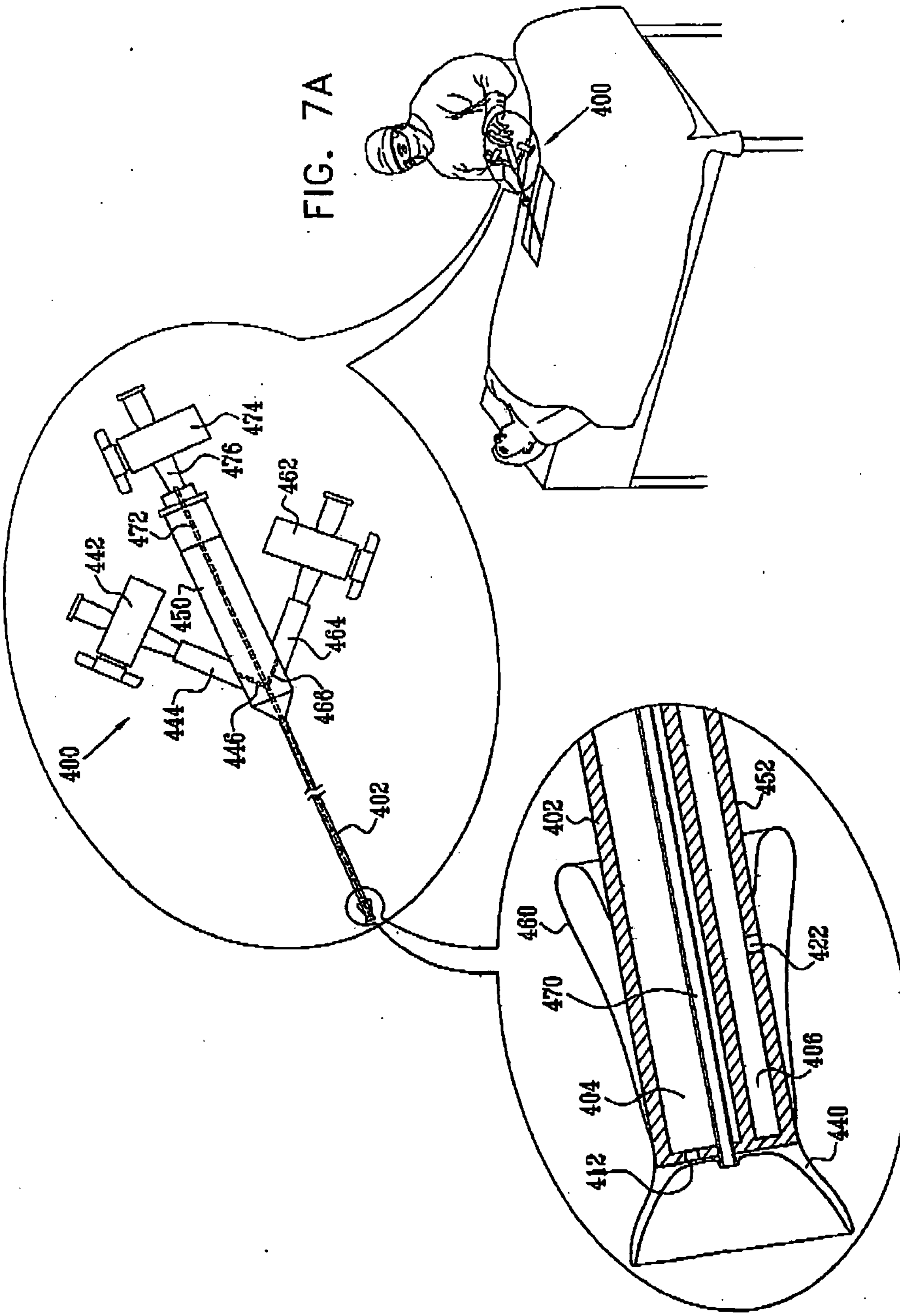
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FIG. 7A

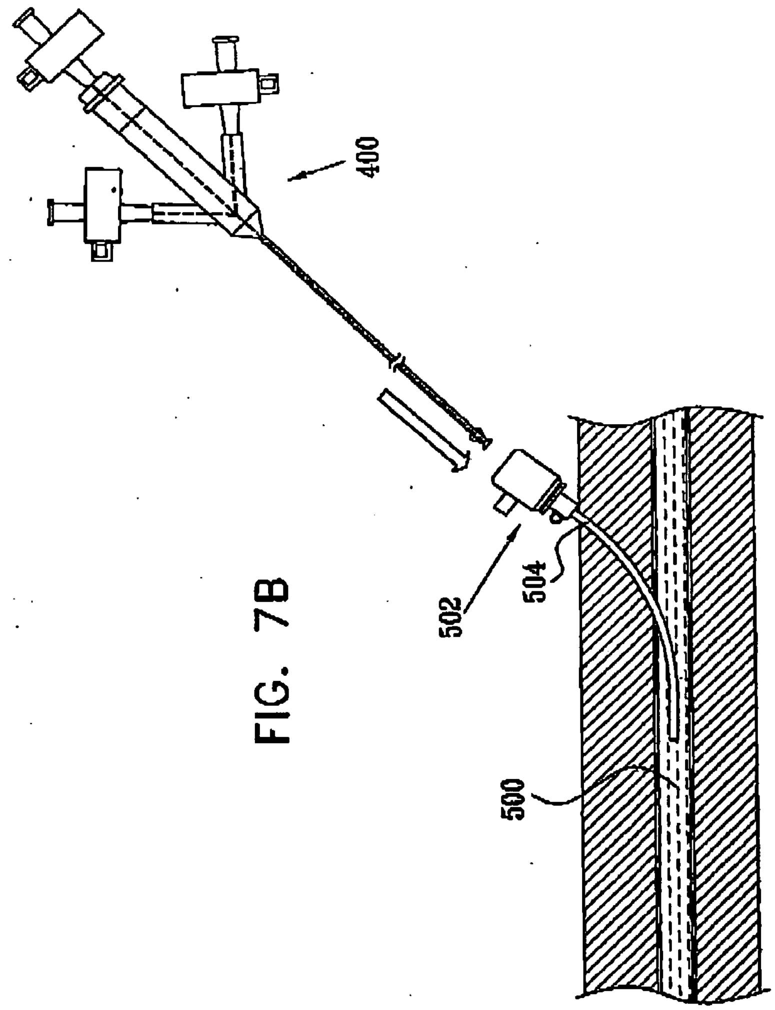
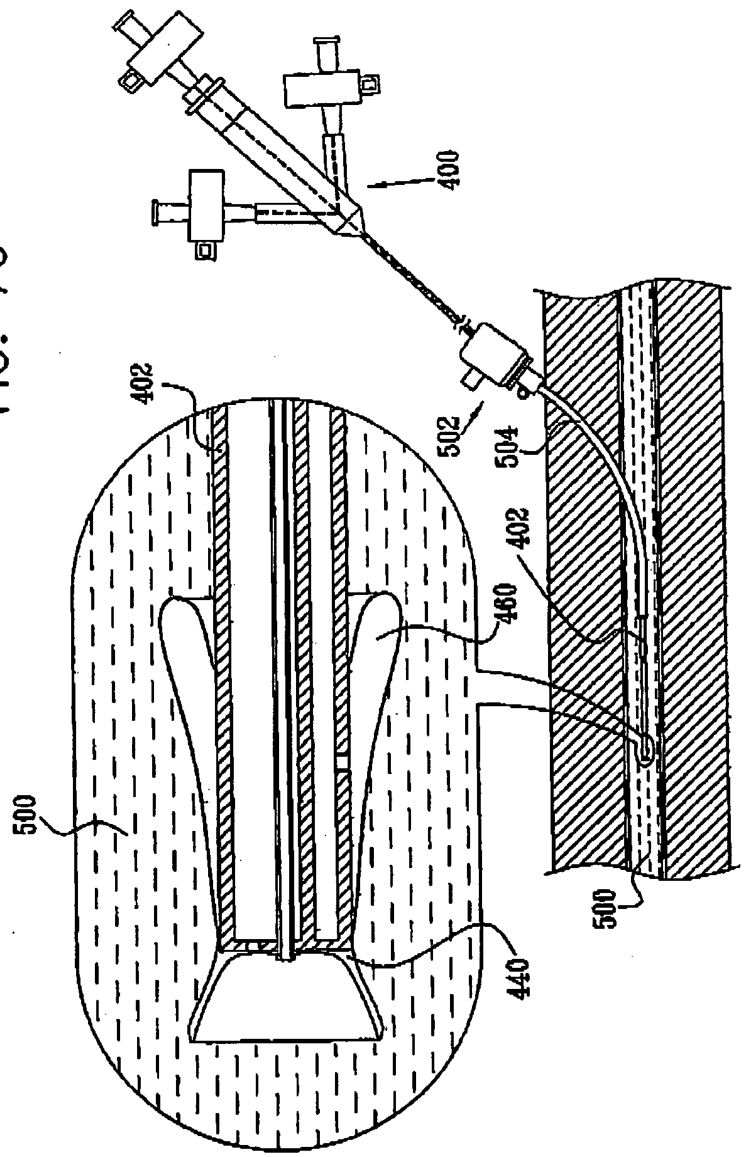


FIG. 7B

FIG. 7C



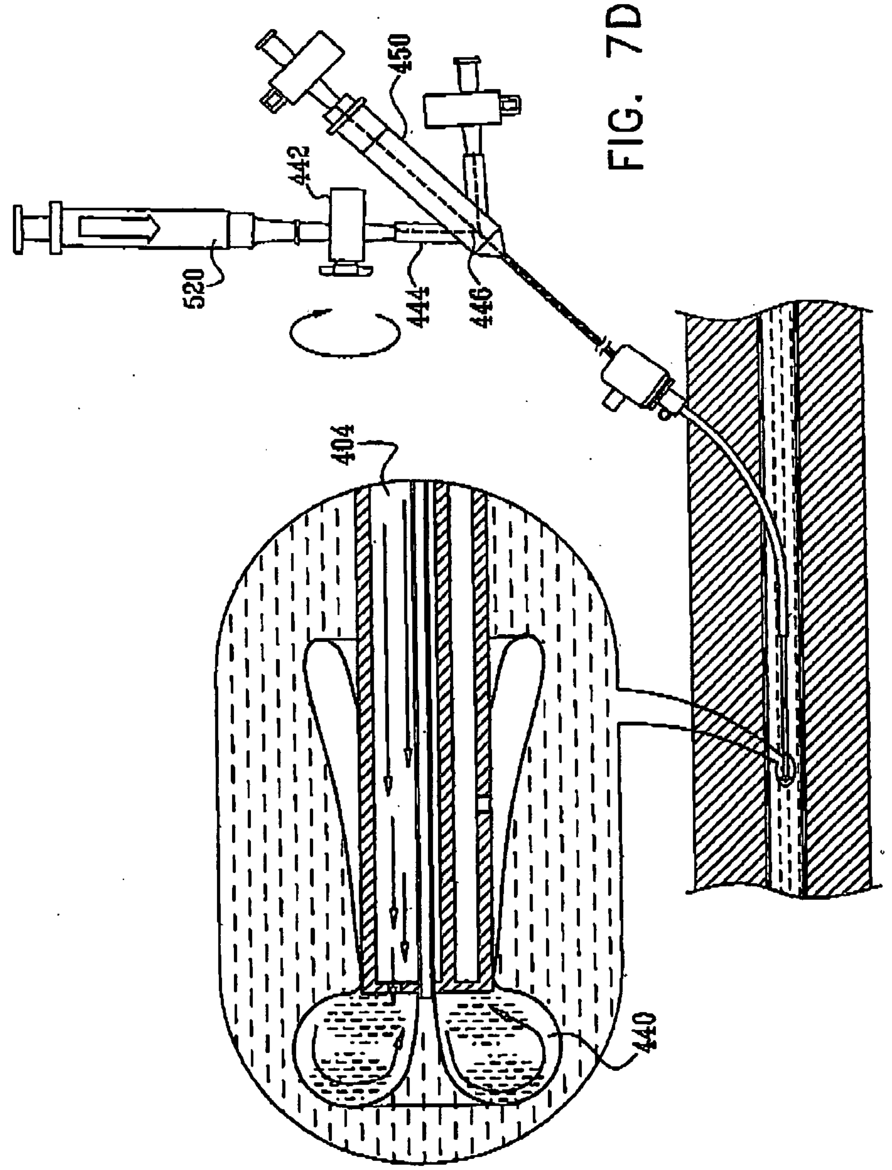


FIG. 7D

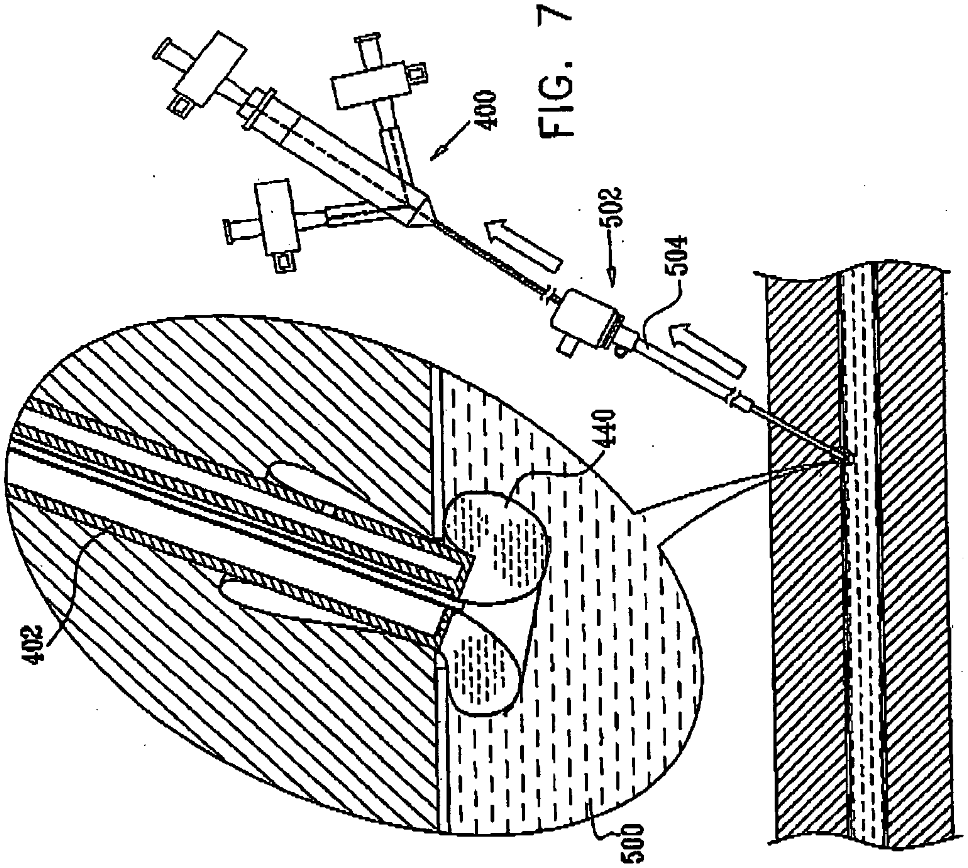


FIG. 7E

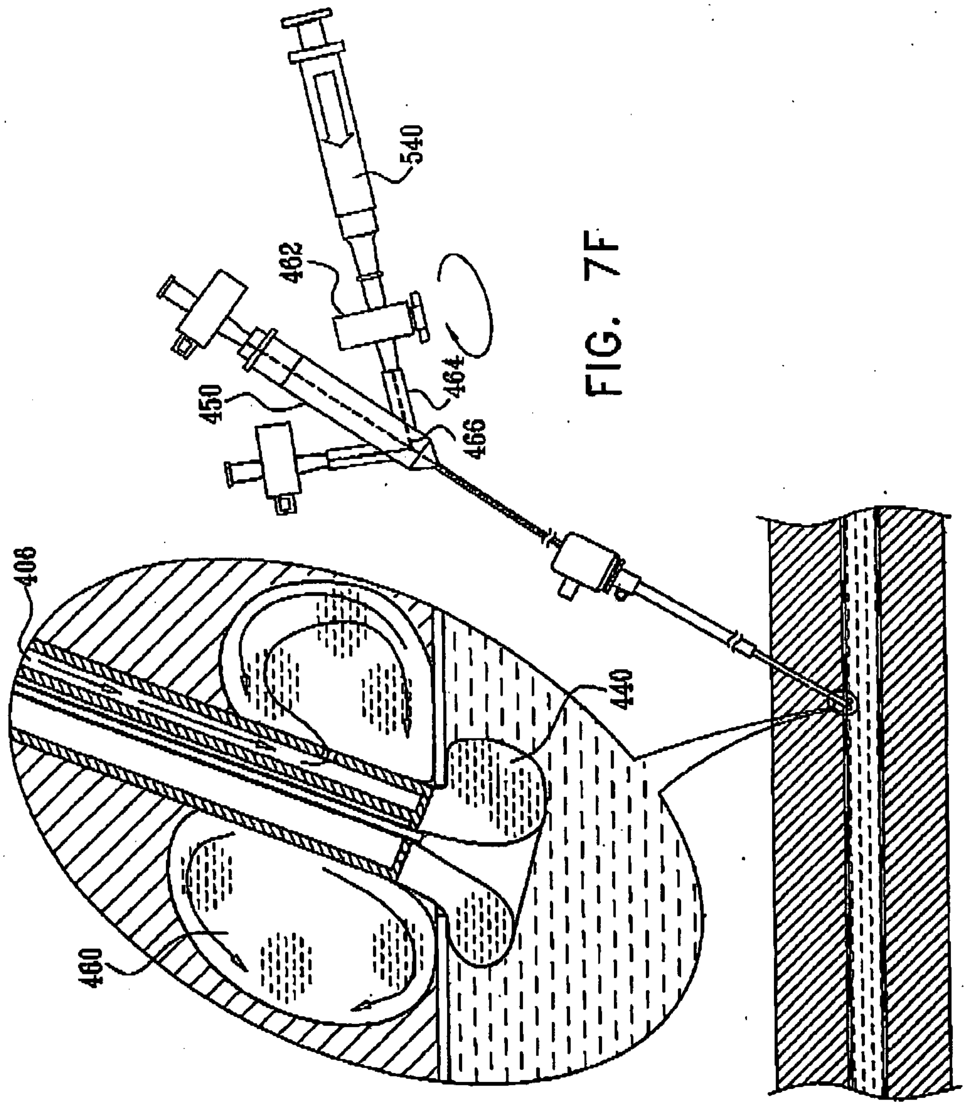


FIG. 7F

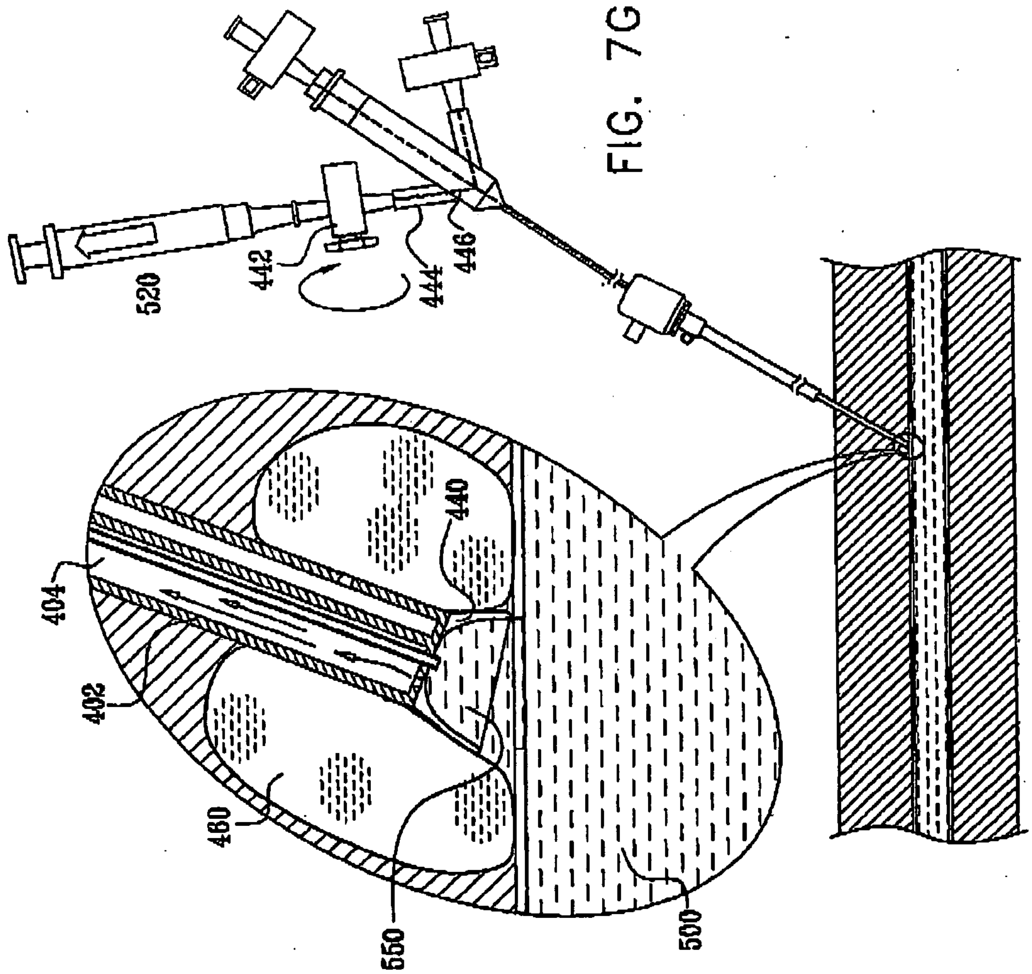


FIG. 7G

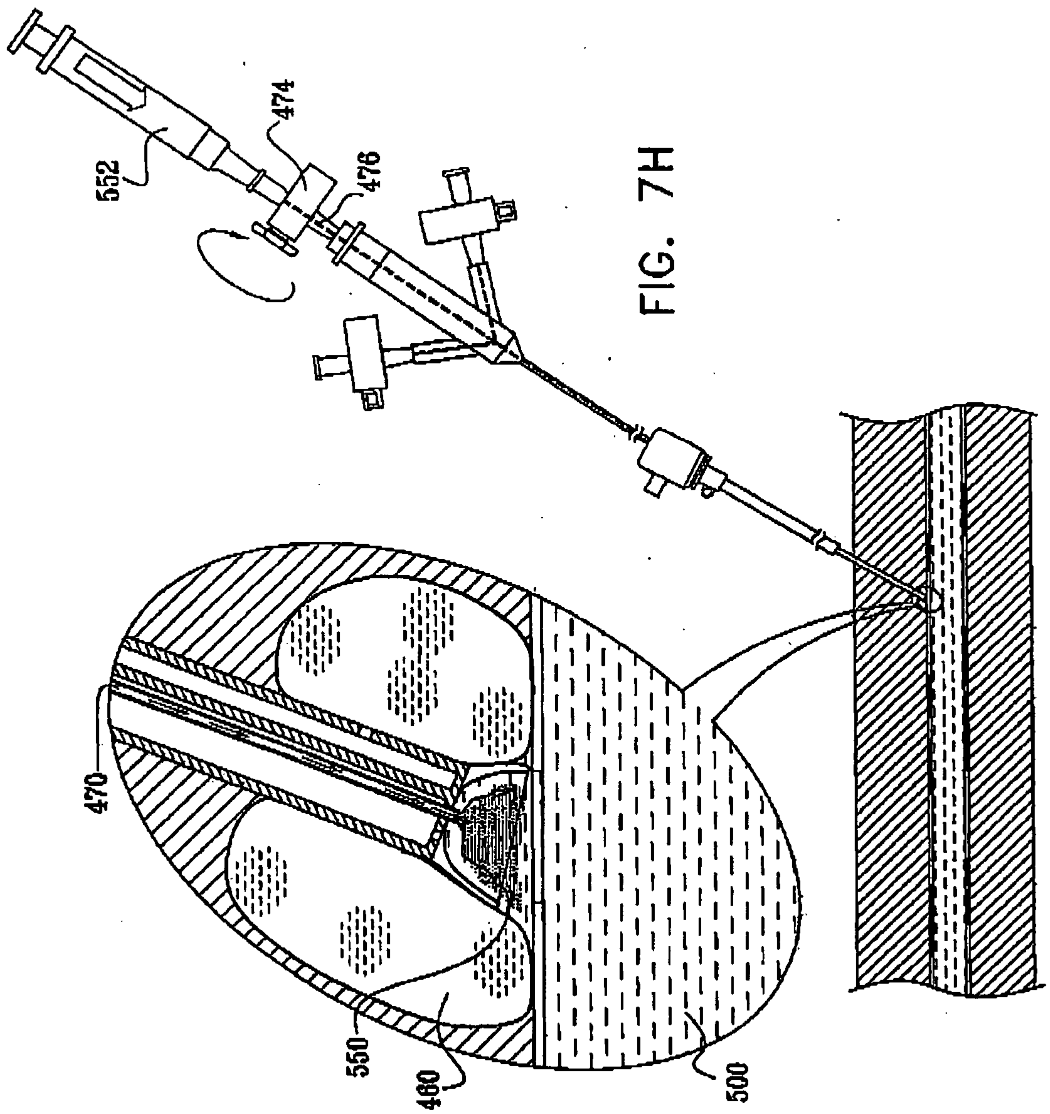


FIG. 7H

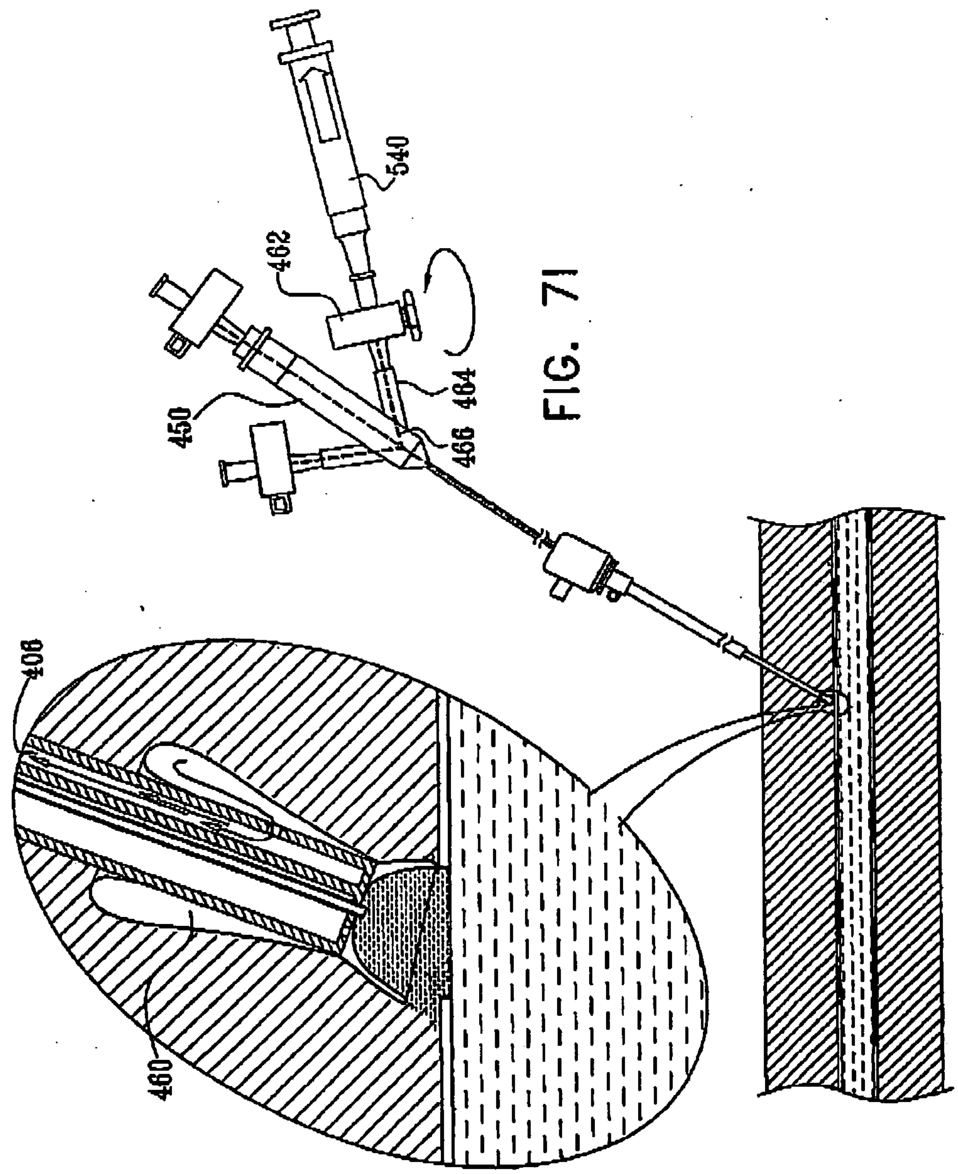


FIG. 71

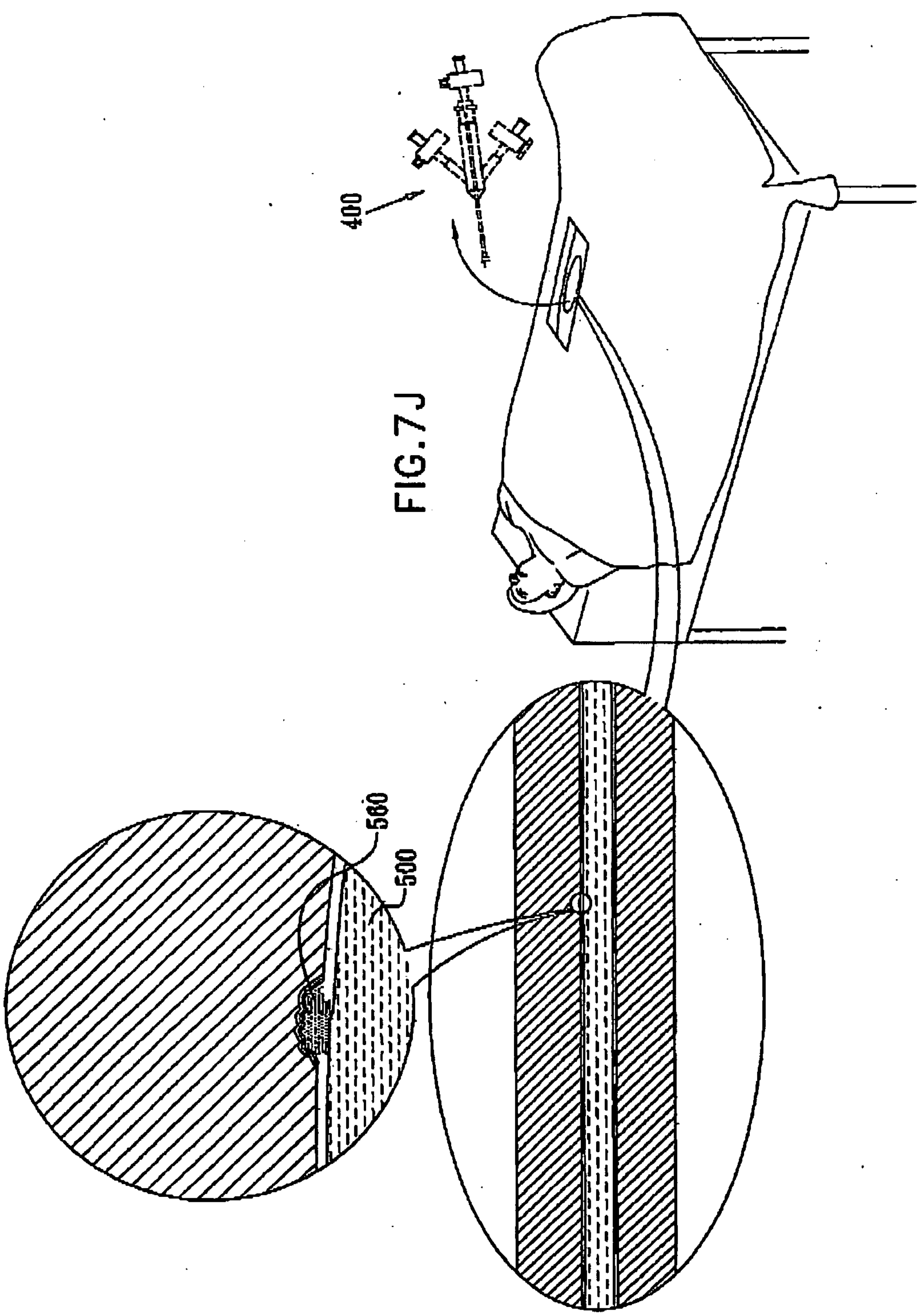


FIG.7J

FIG. 8A

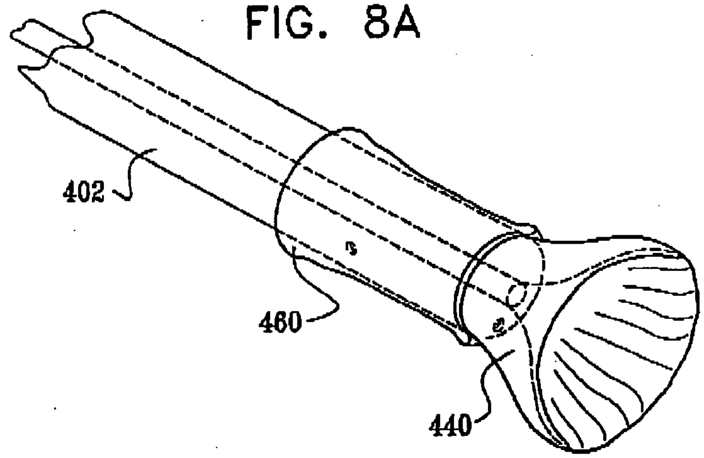


FIG.8B

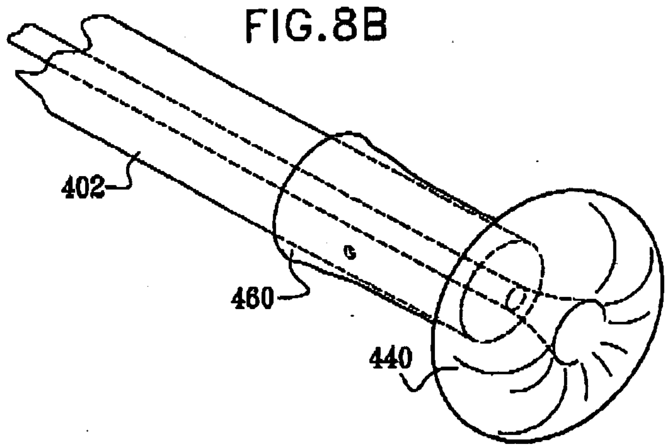


FIG. 8C

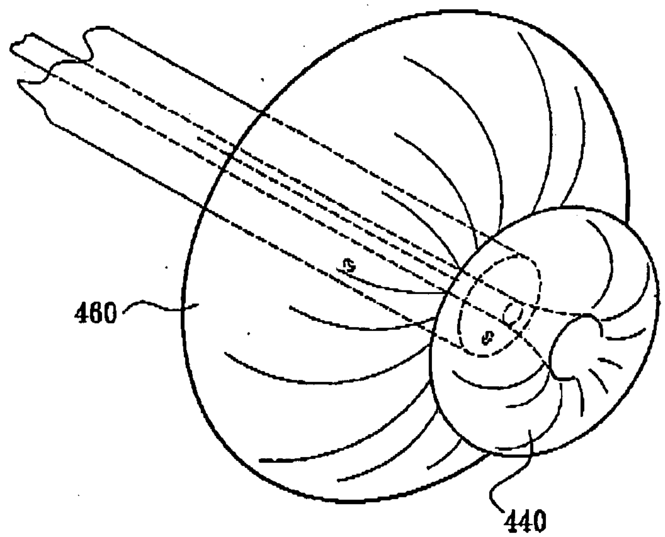
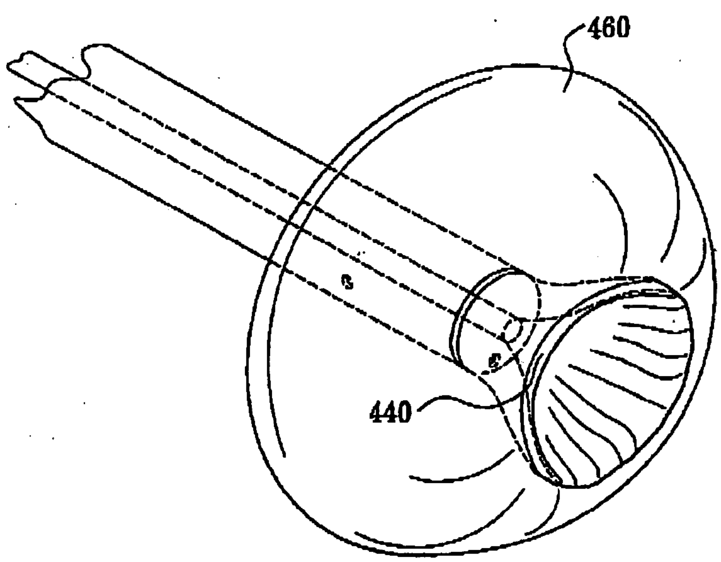


FIG. 8D



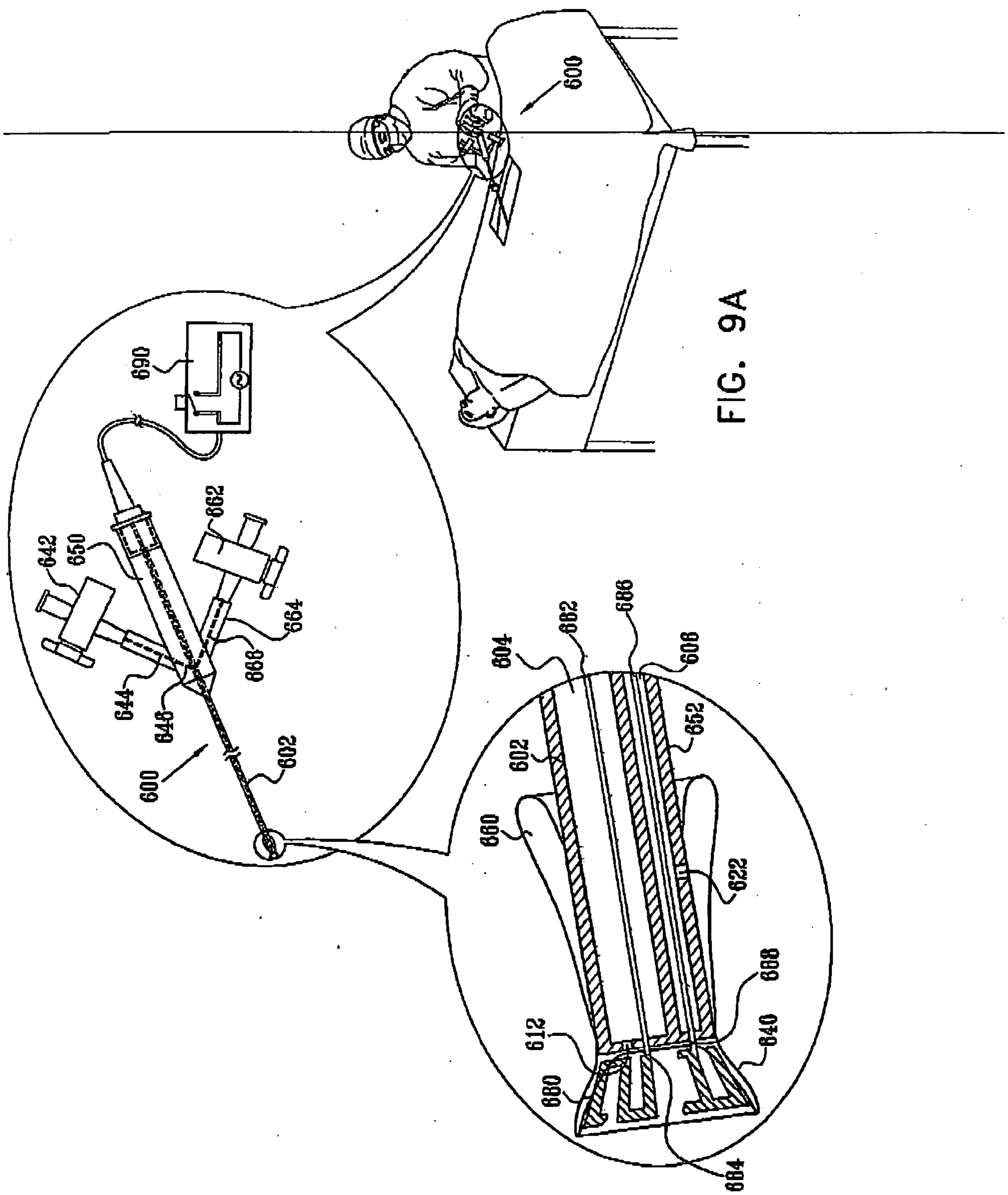

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FIG. 9A

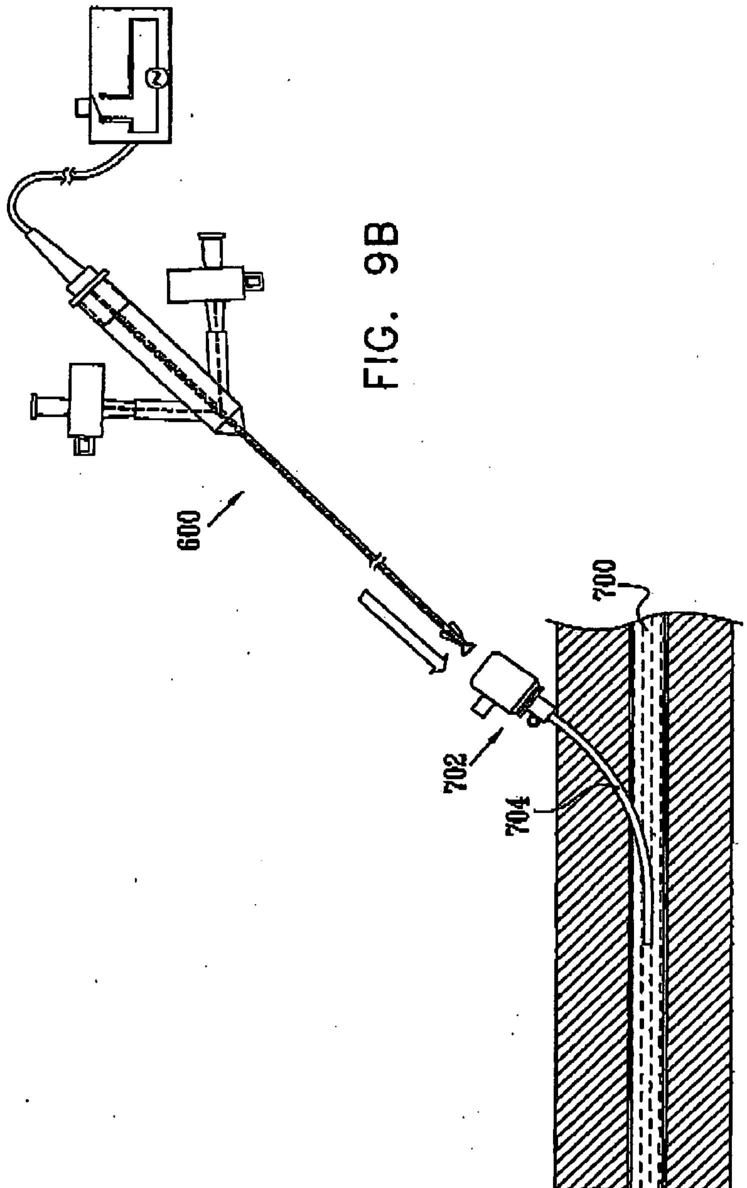


FIG. 9B

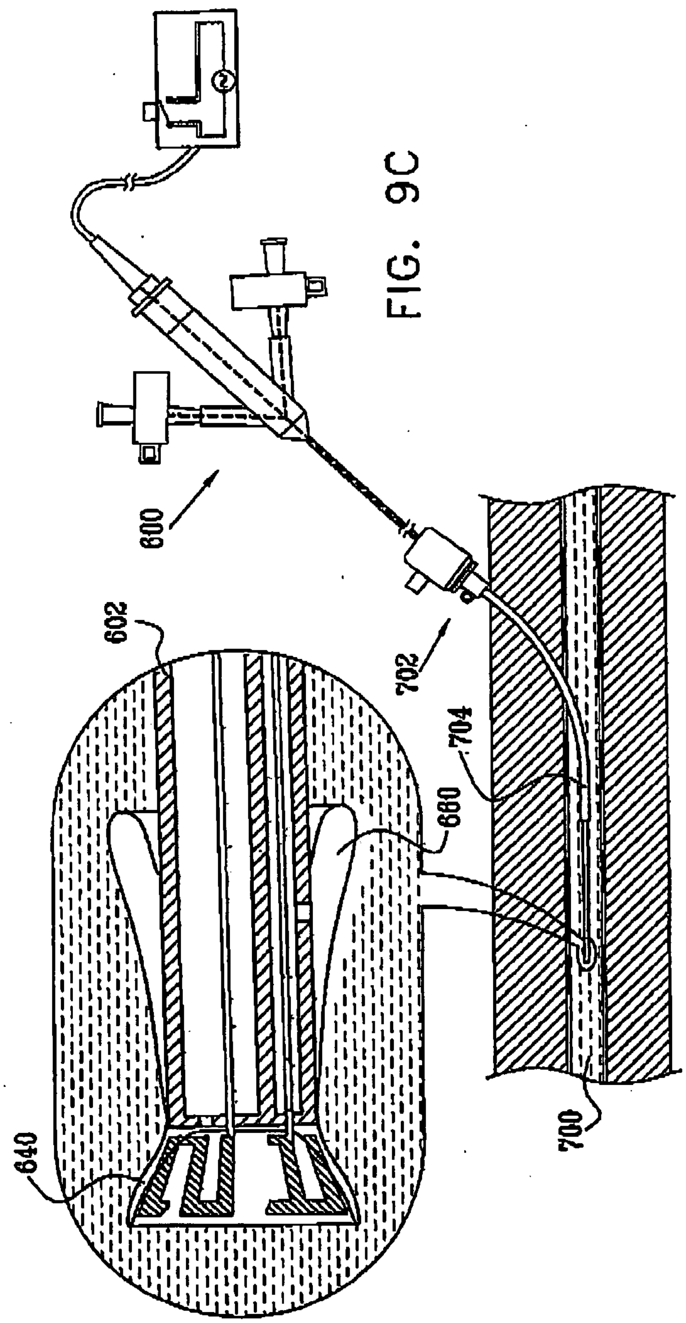


FIG. 9C

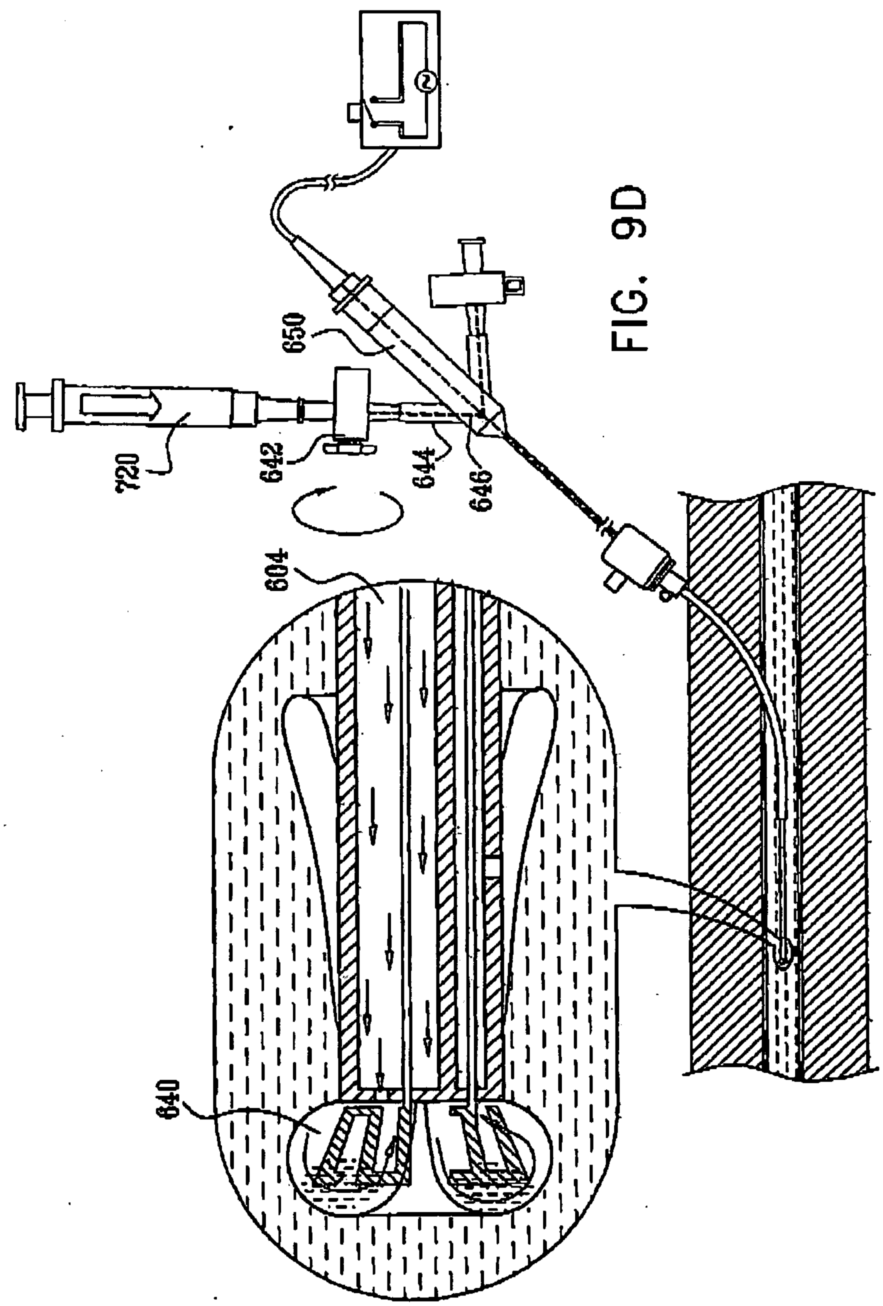


FIG. 9D

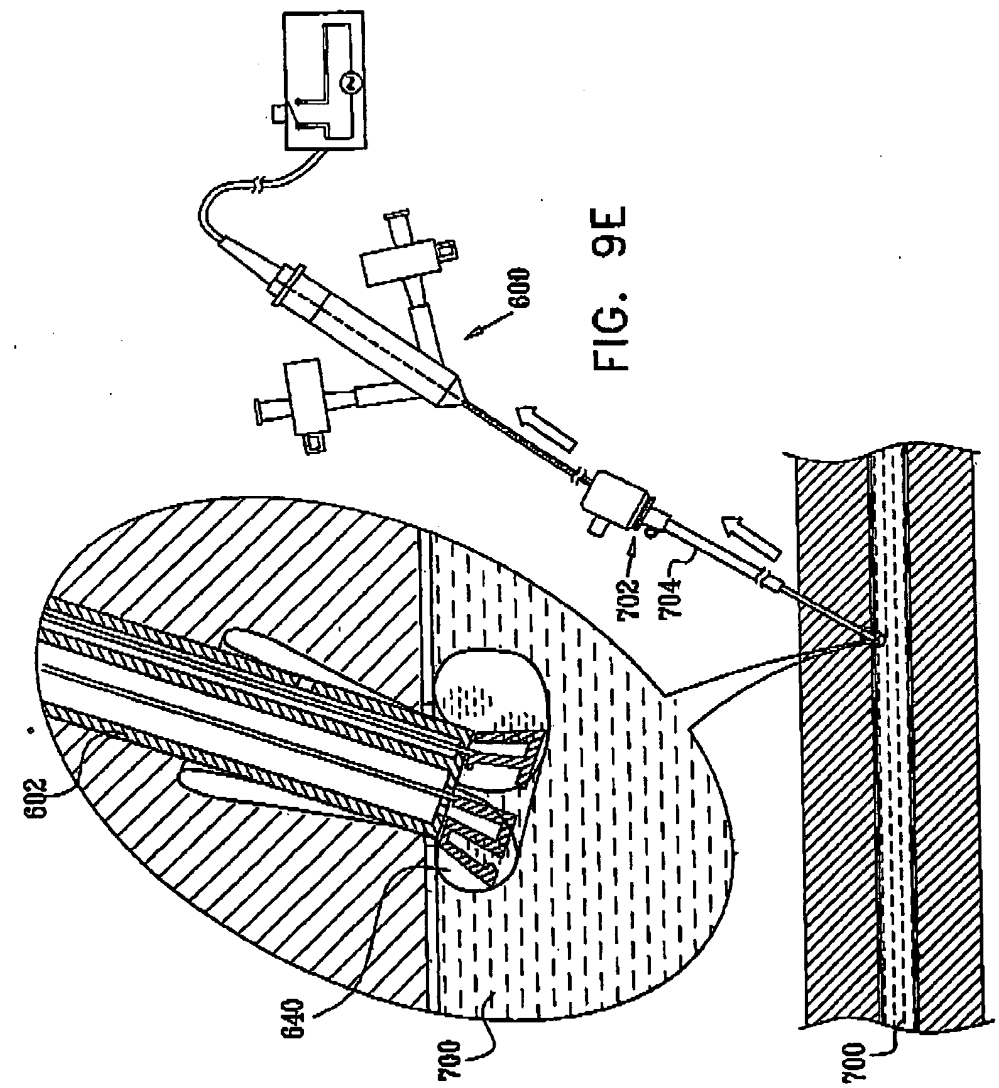


FIG. 9E

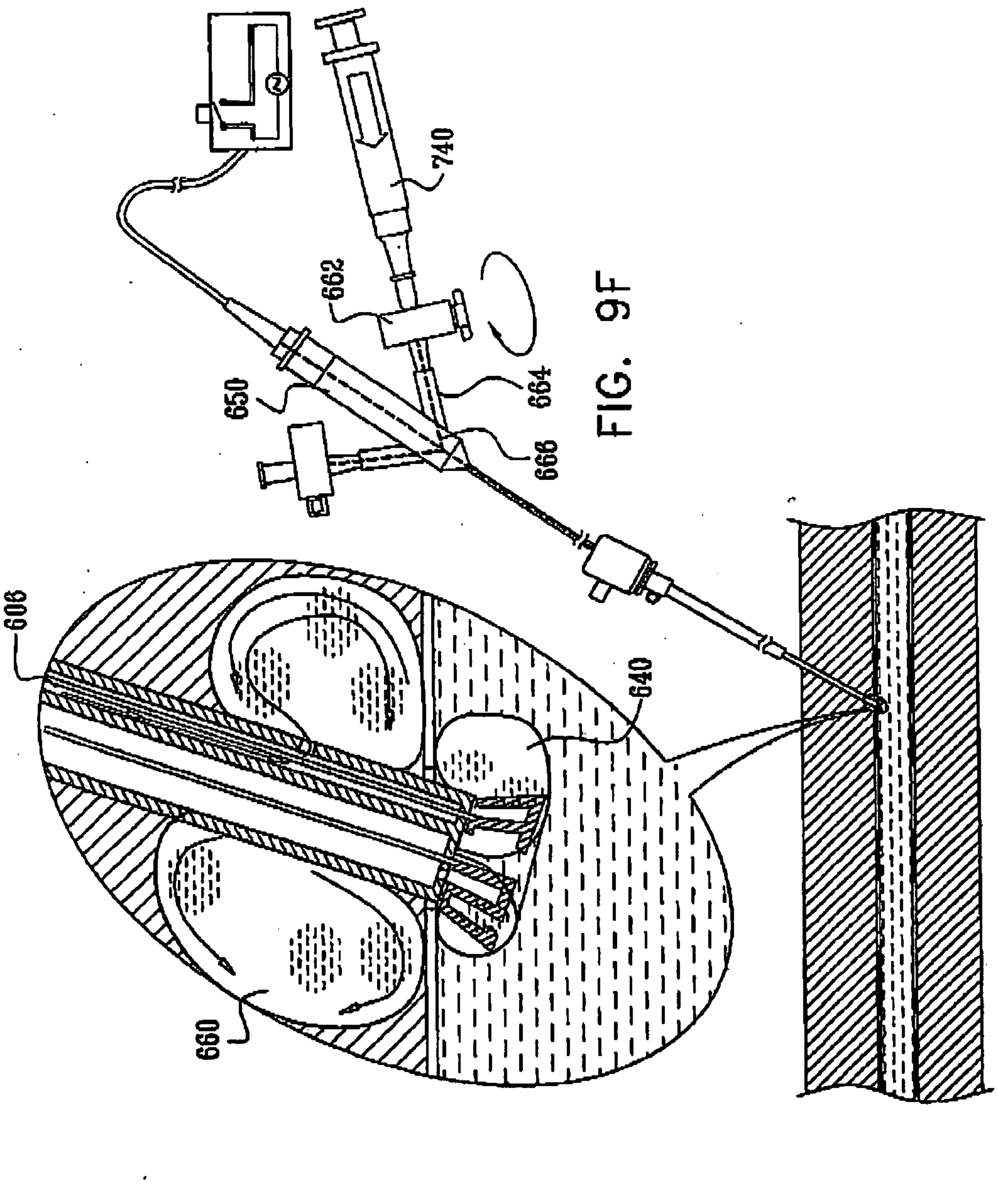


FIG. 9F

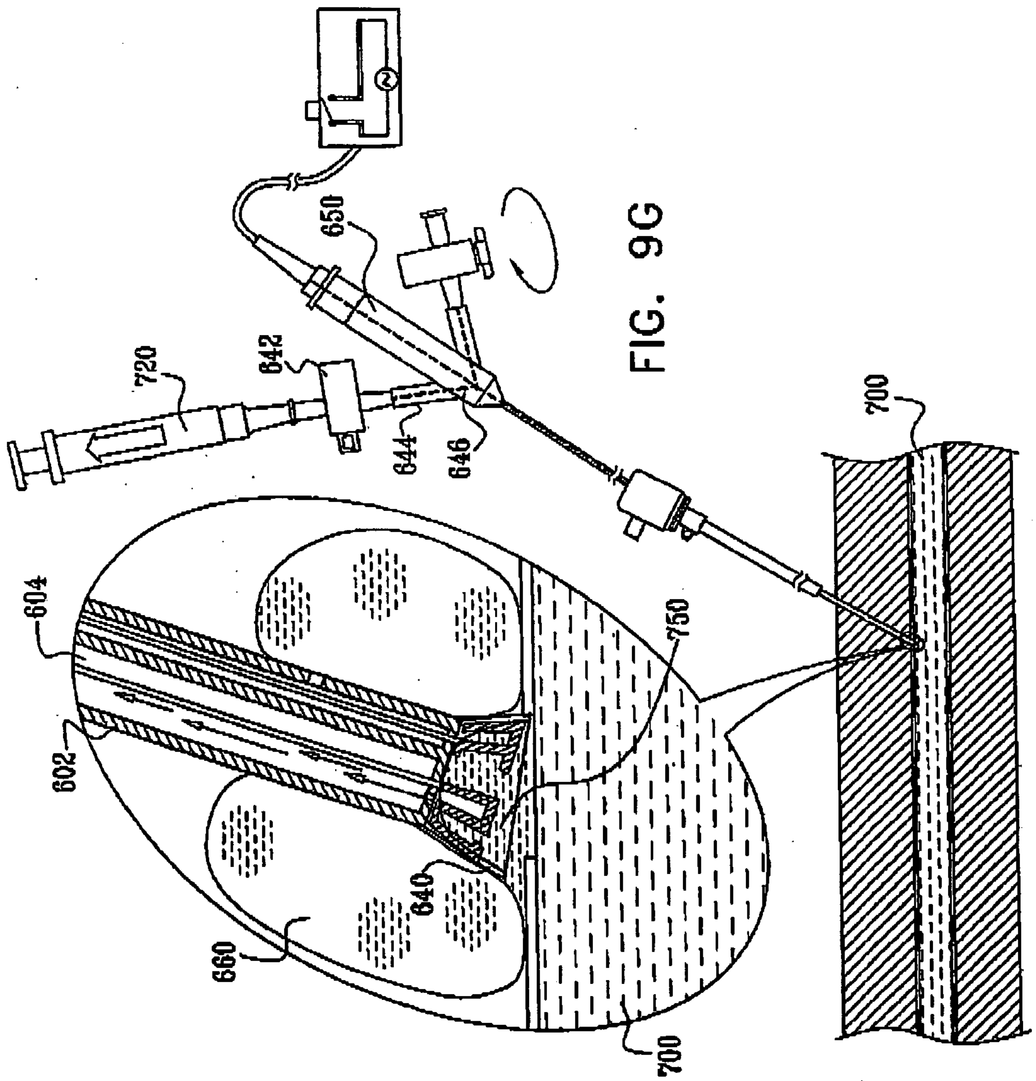


FIG. 9G

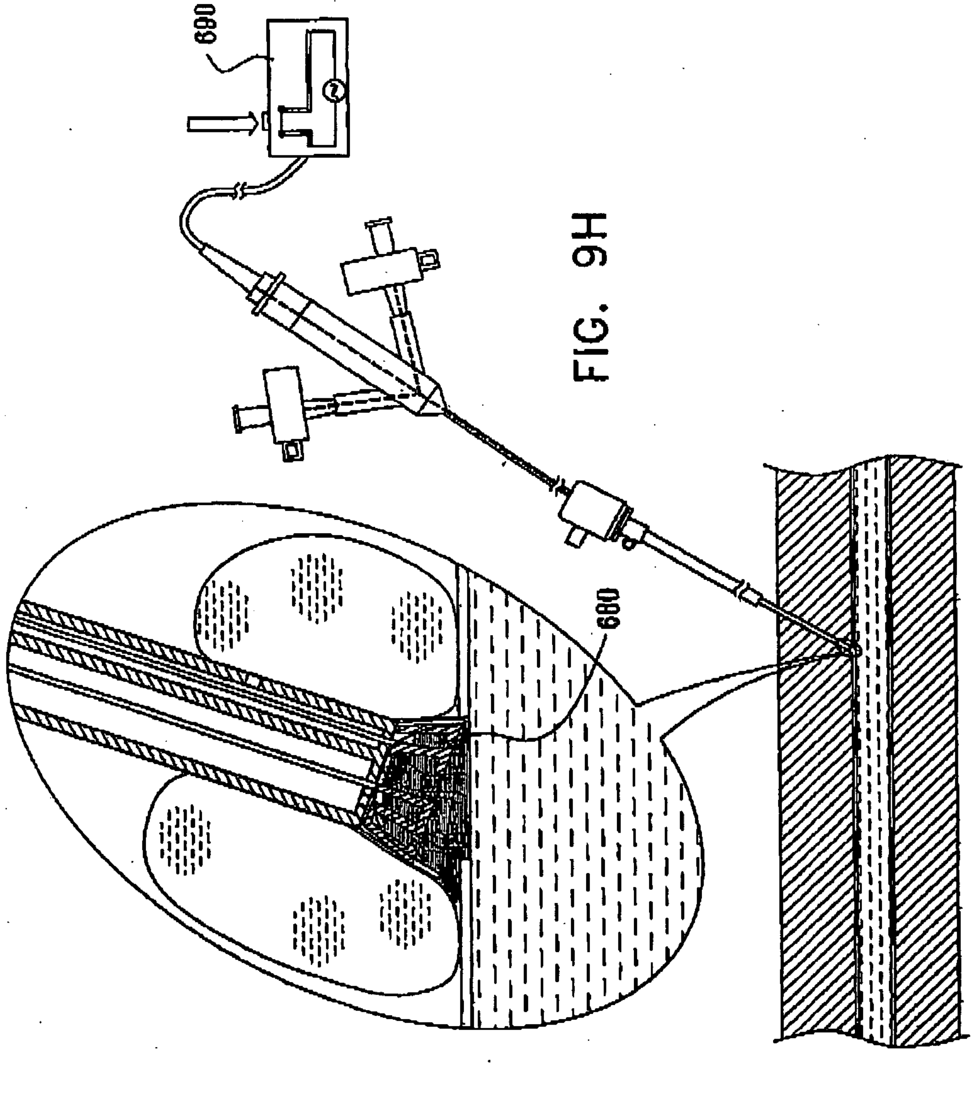


FIG. 9H

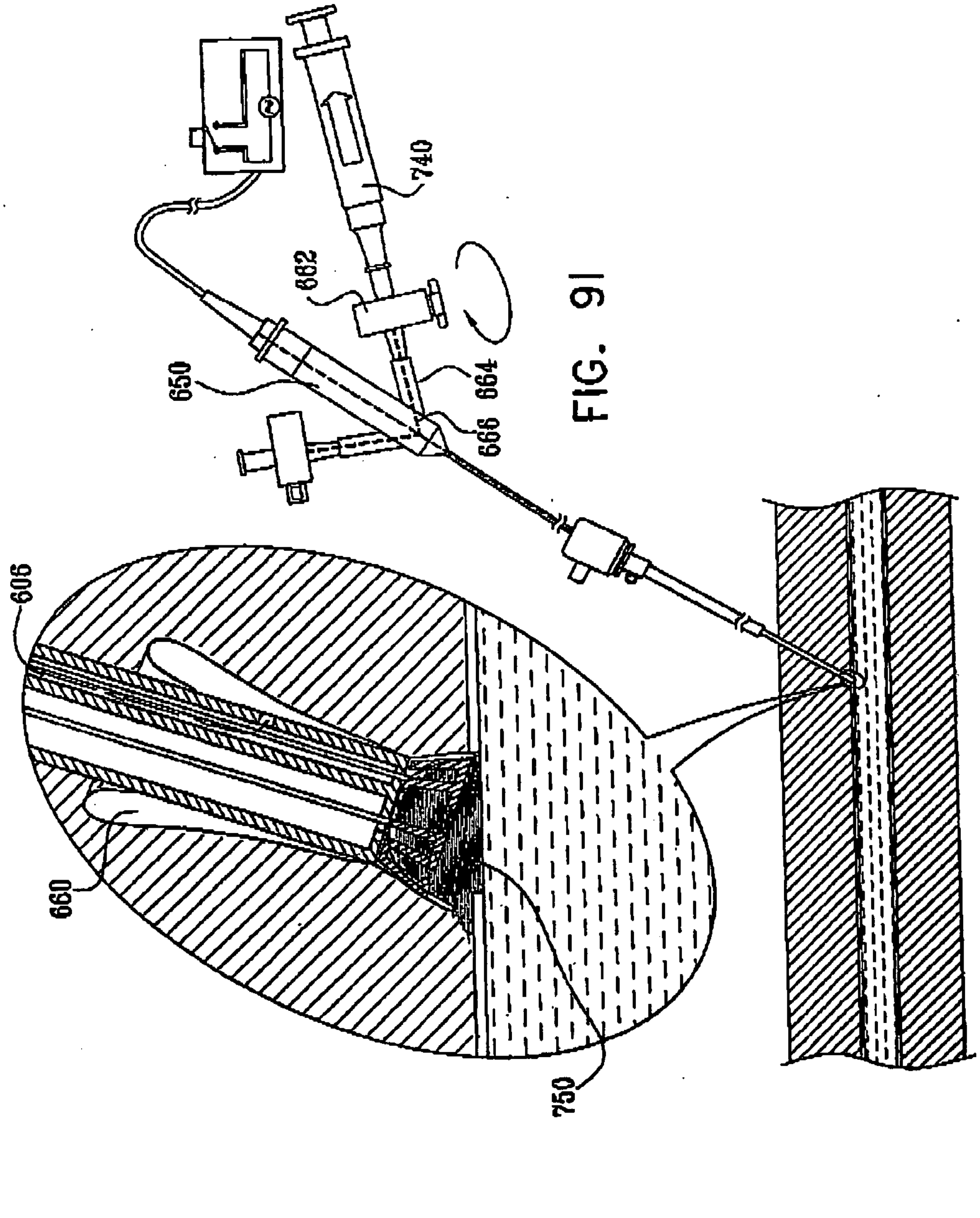


FIG. 9I

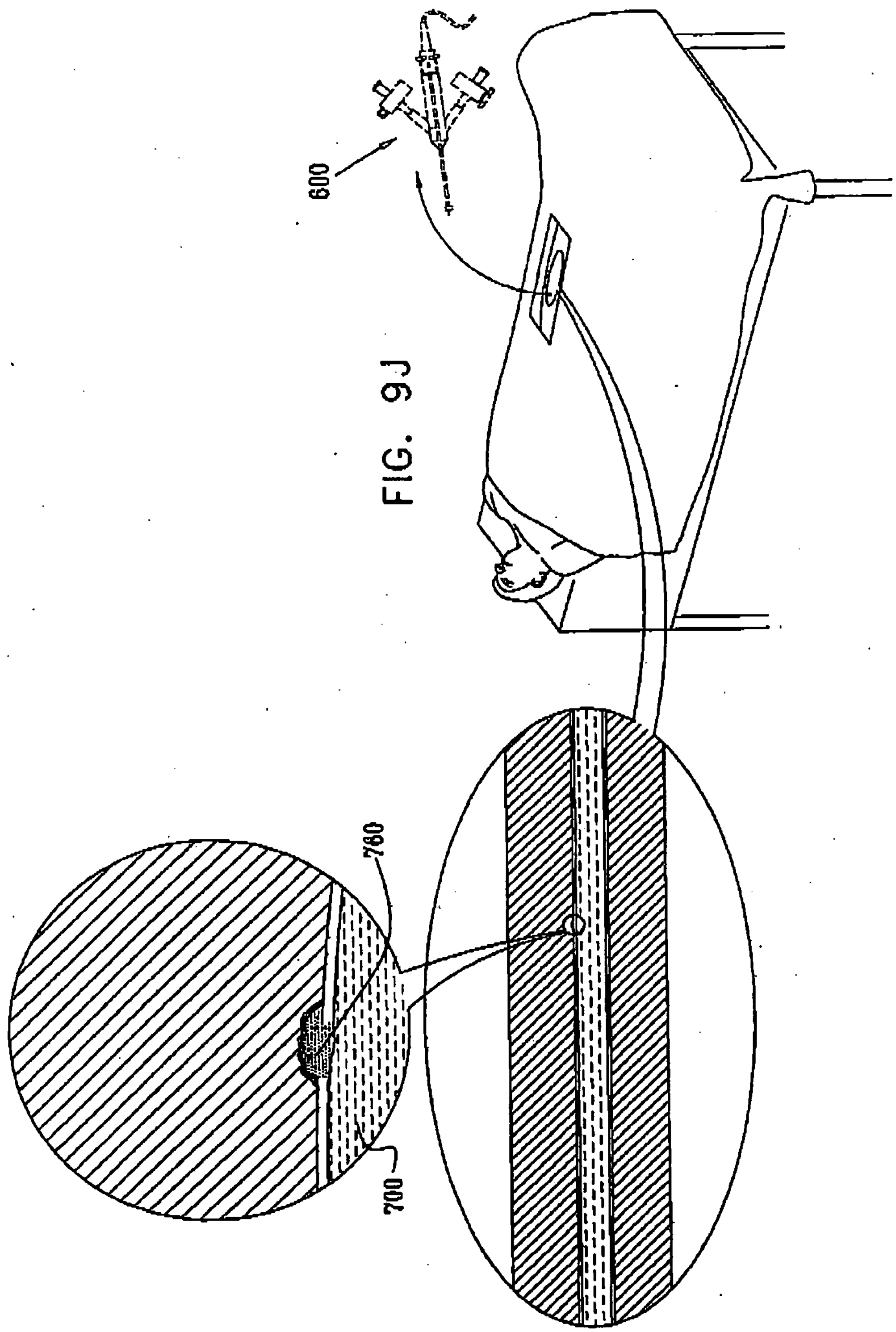


FIG. 9J

FIG. 10A

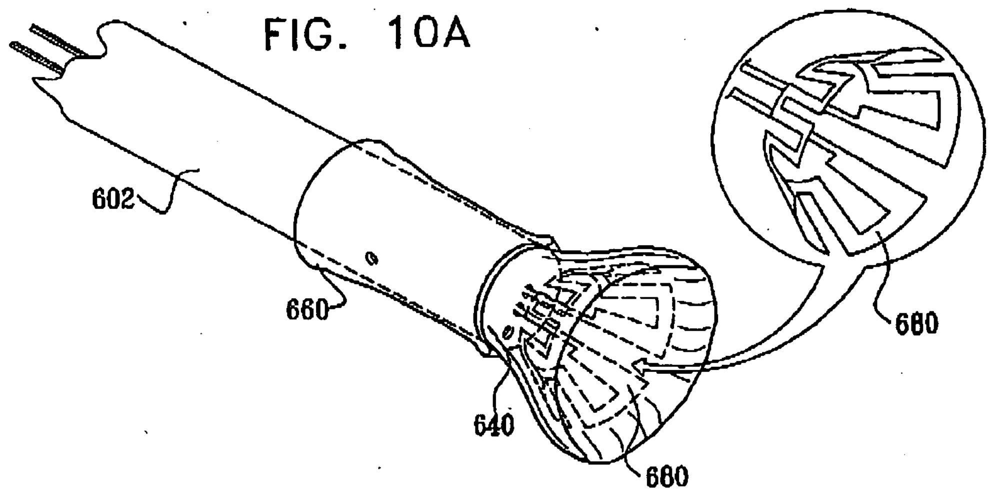


FIG.10B

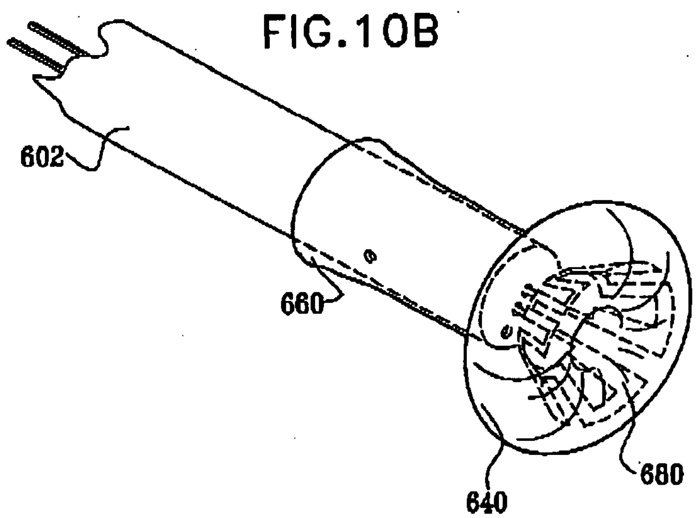


FIG. 10C

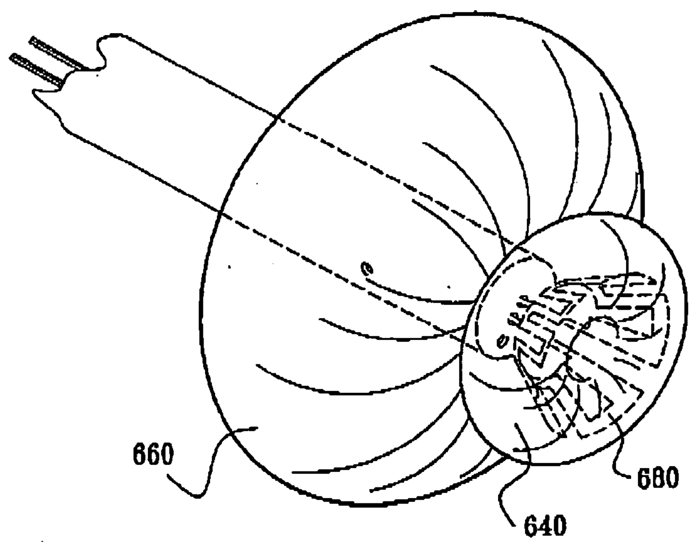
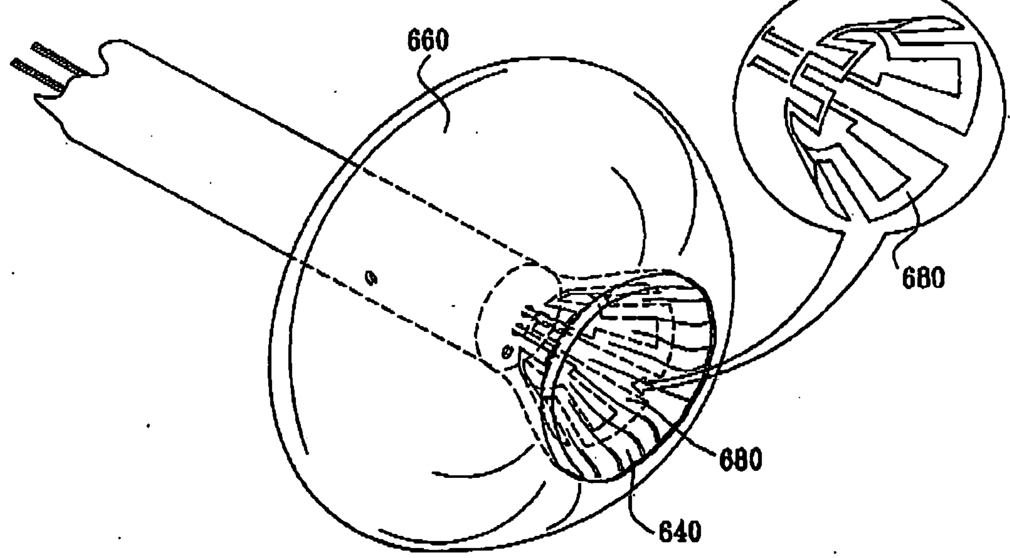


FIG. 10D



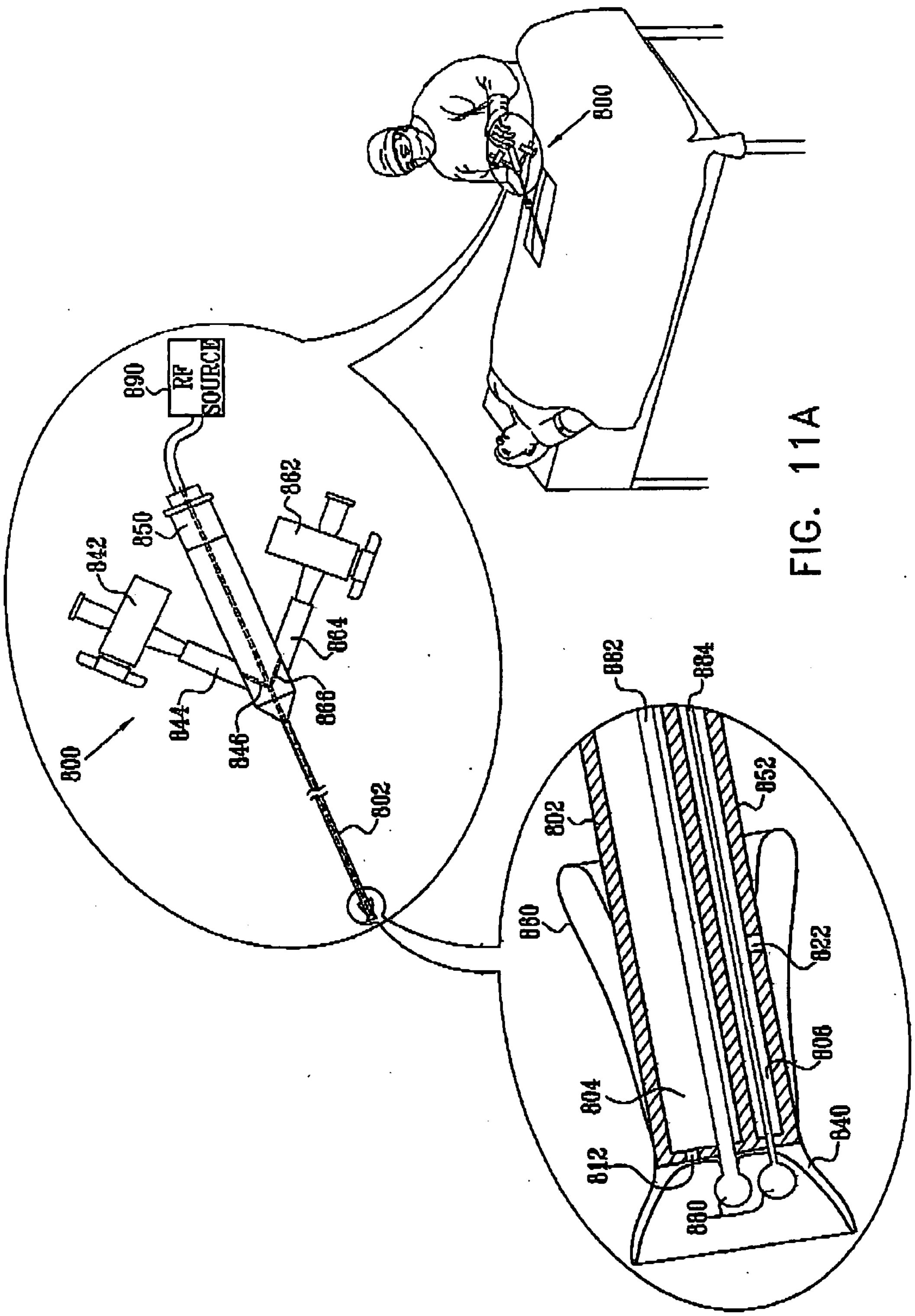

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FIG. 11A

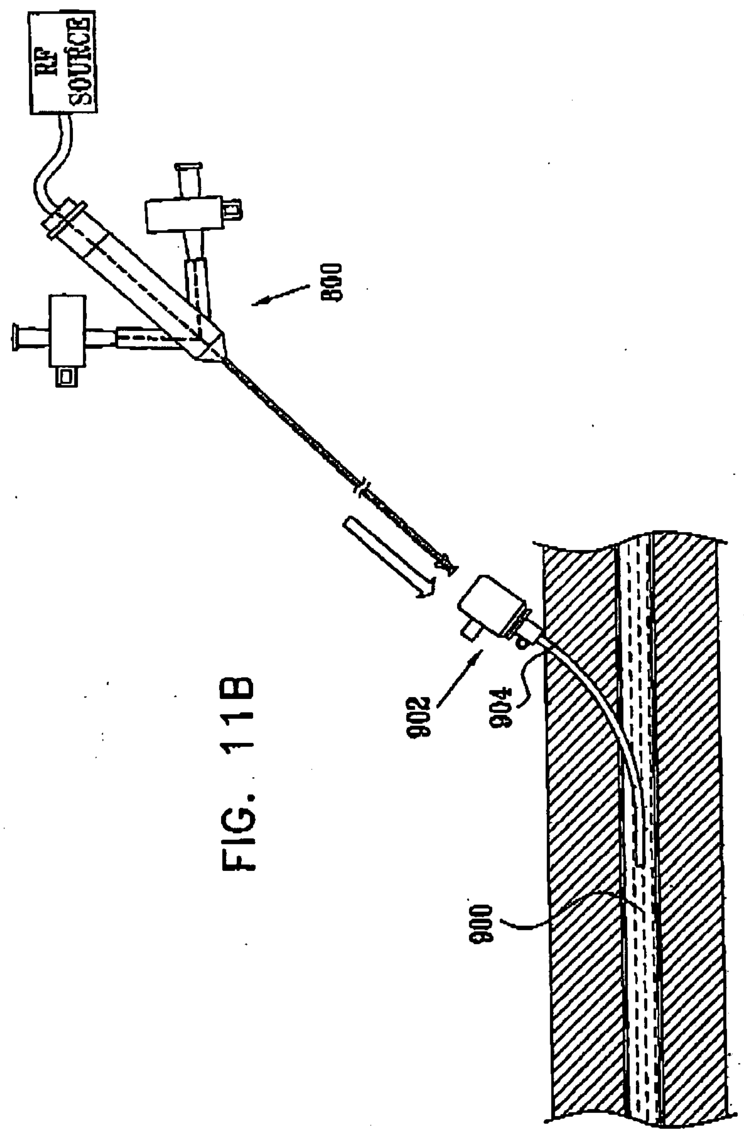
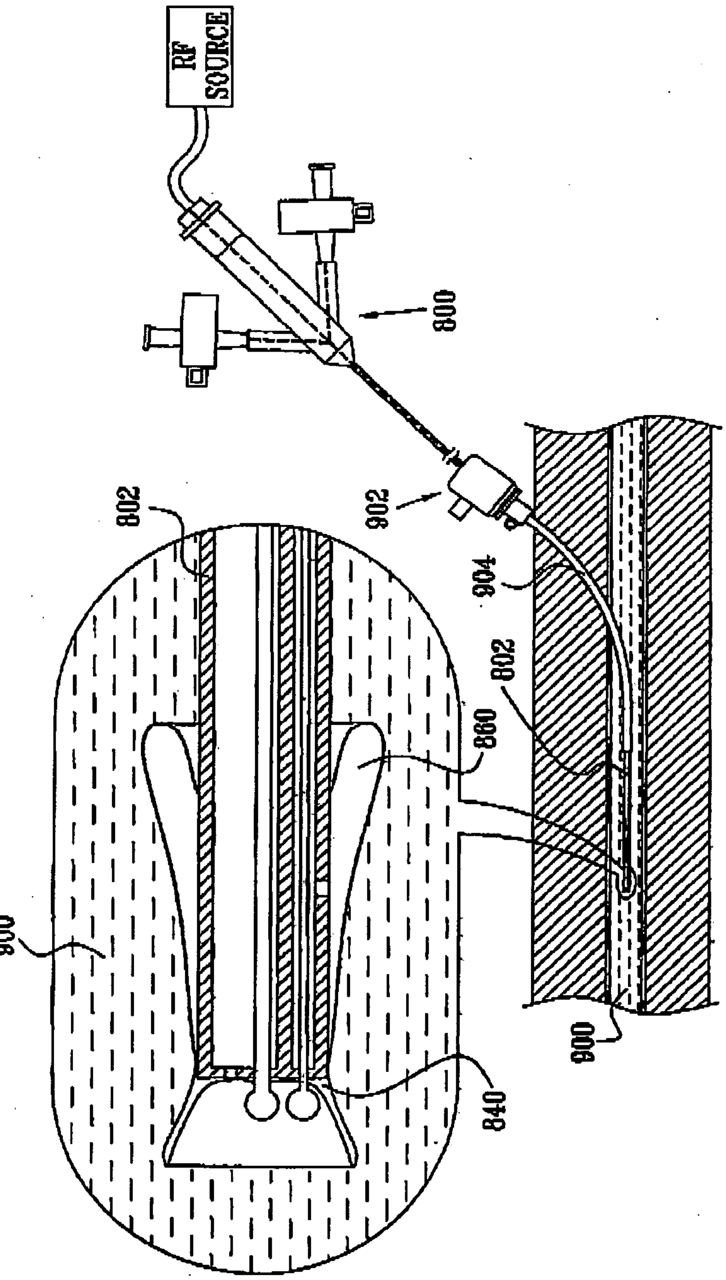


FIG. 11B

FIG. 11C



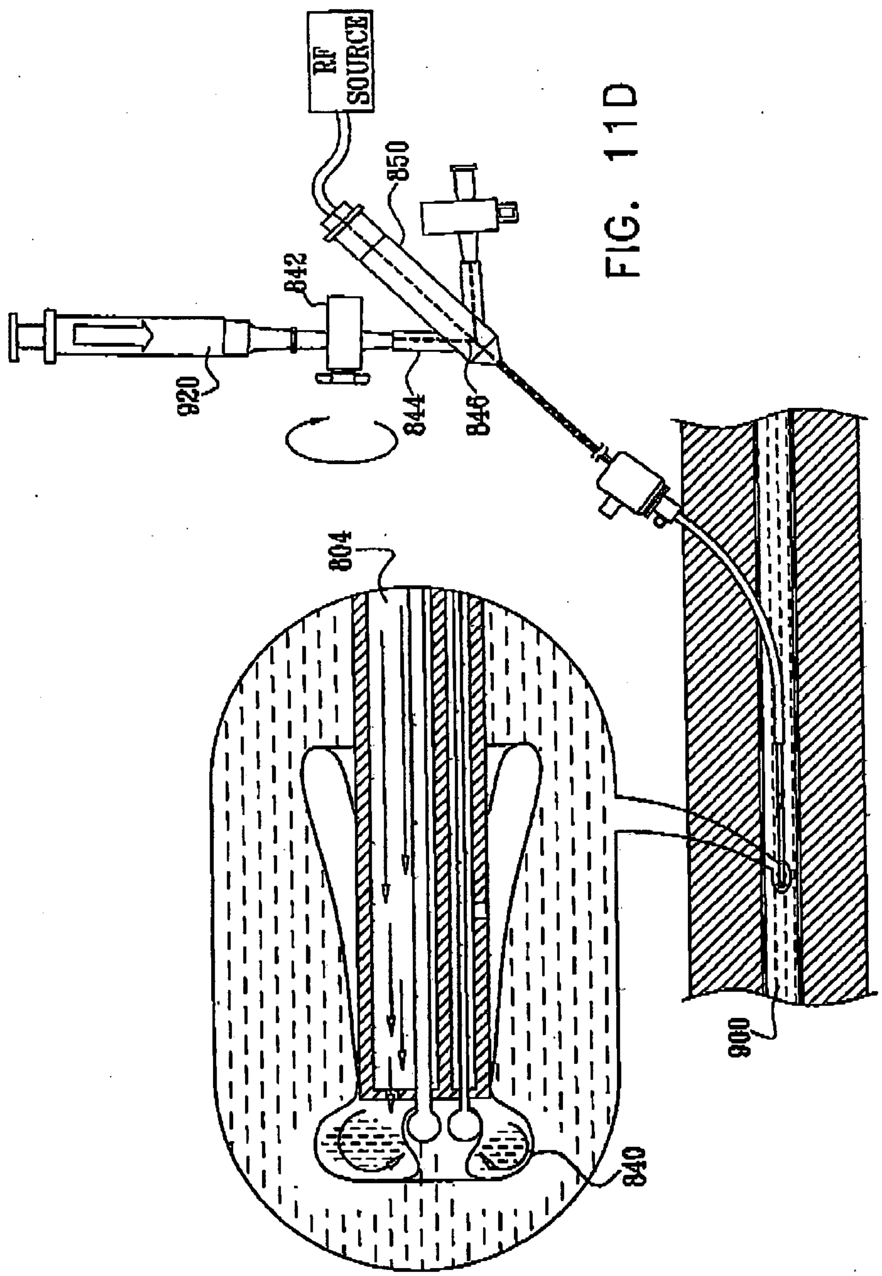


FIG. 11D

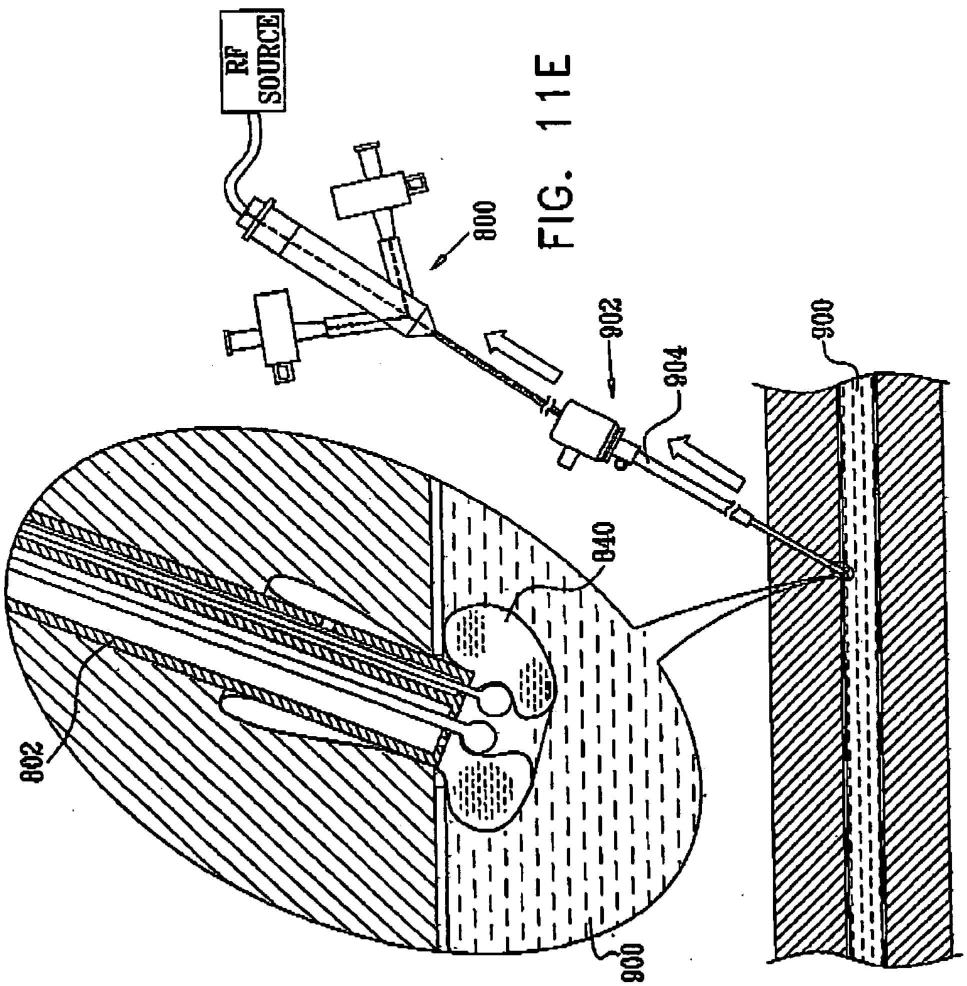


FIG. 11E

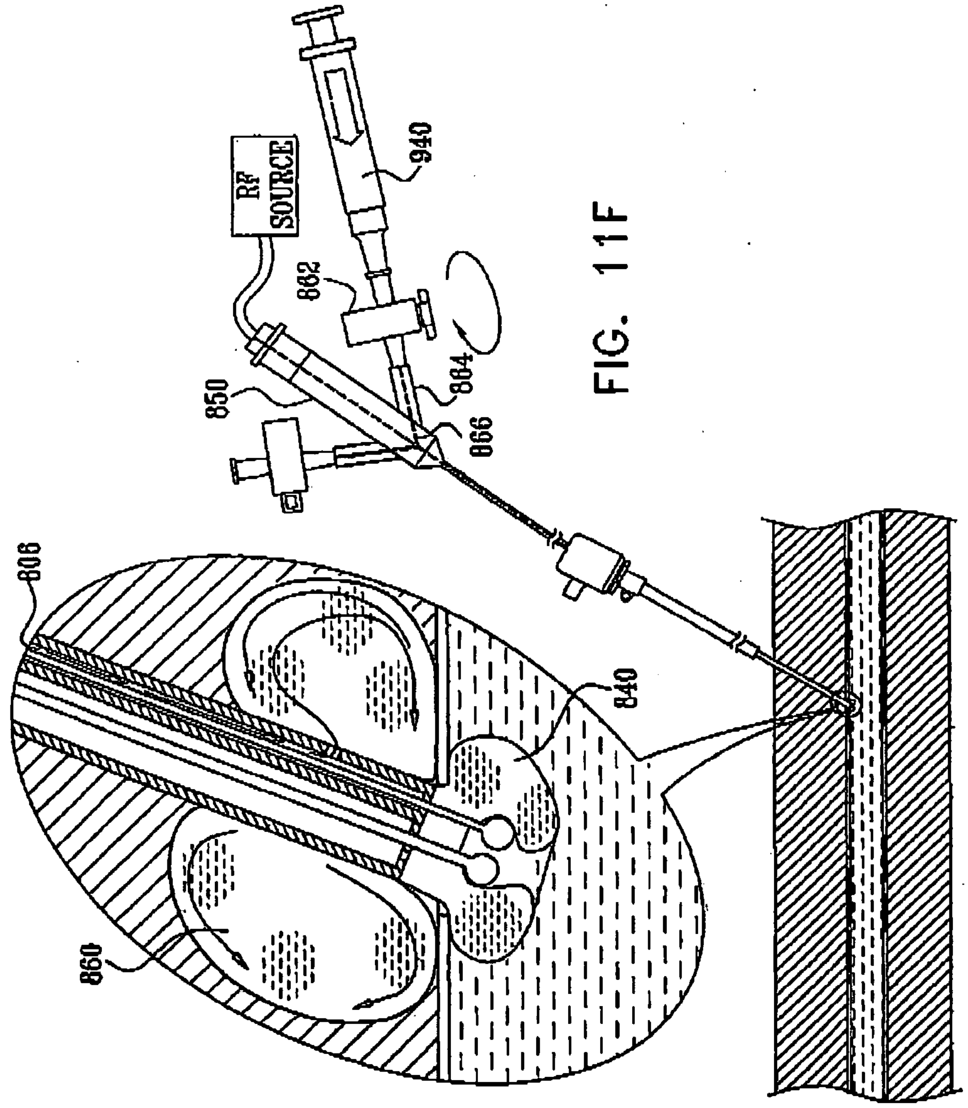


FIG. 11F

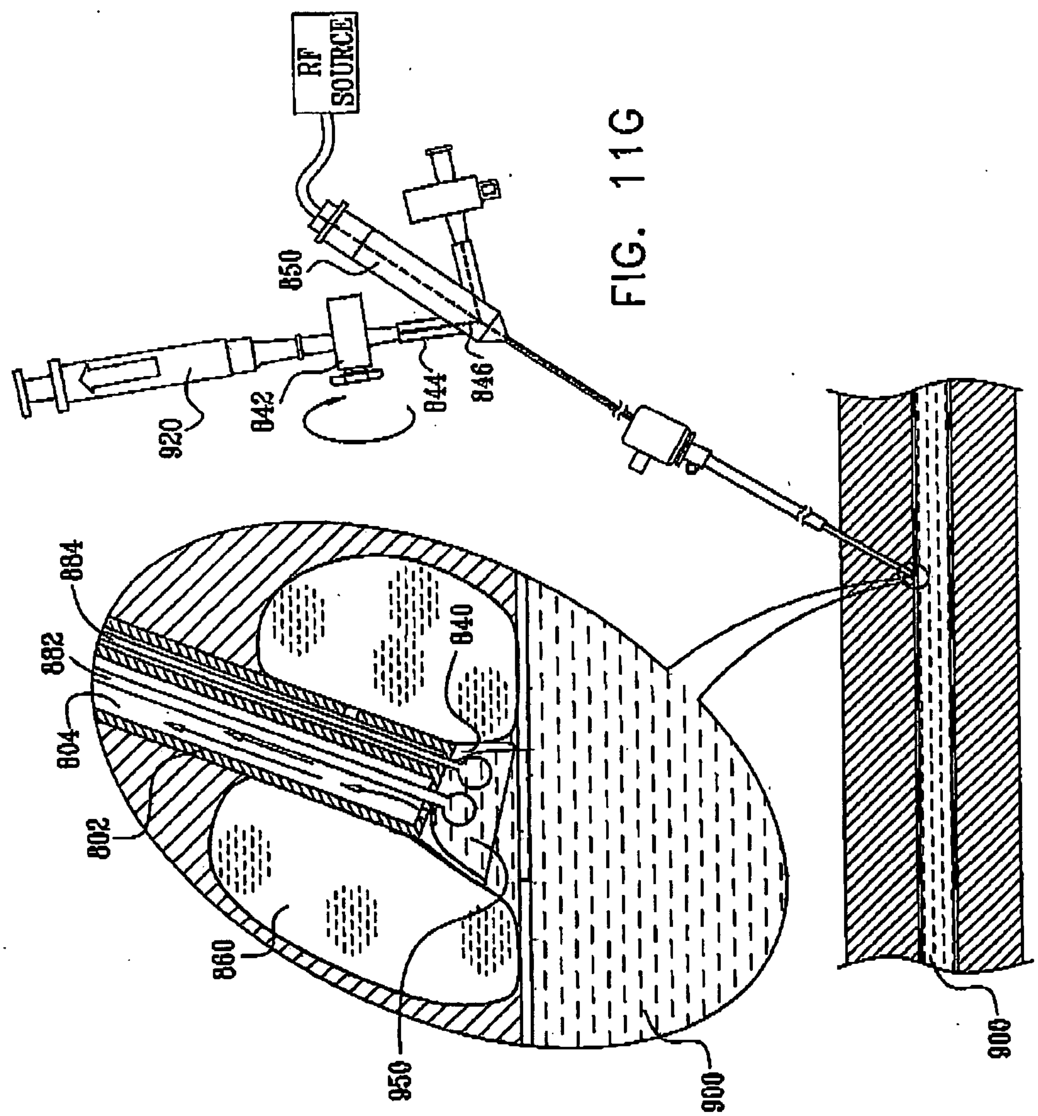

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FIG. 11G

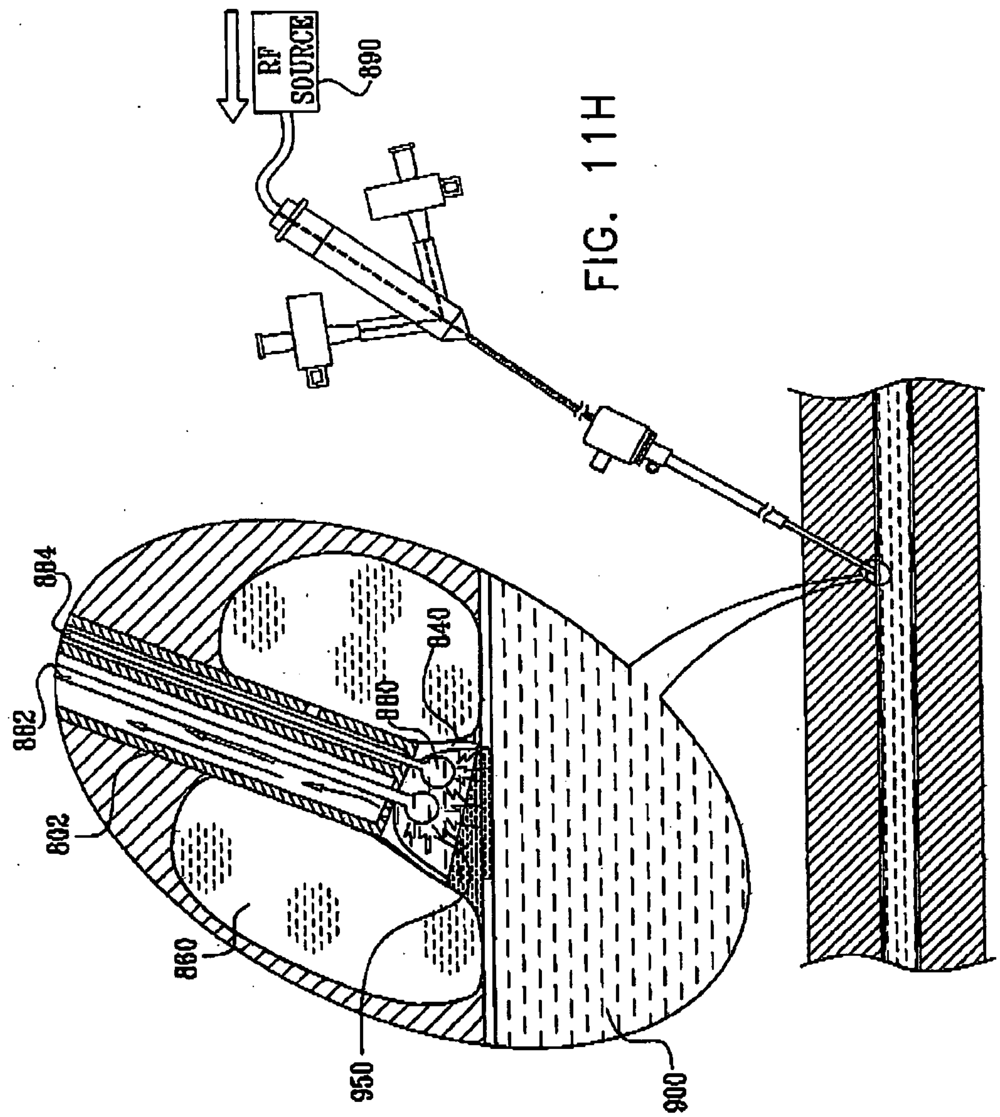


FIG. 11H

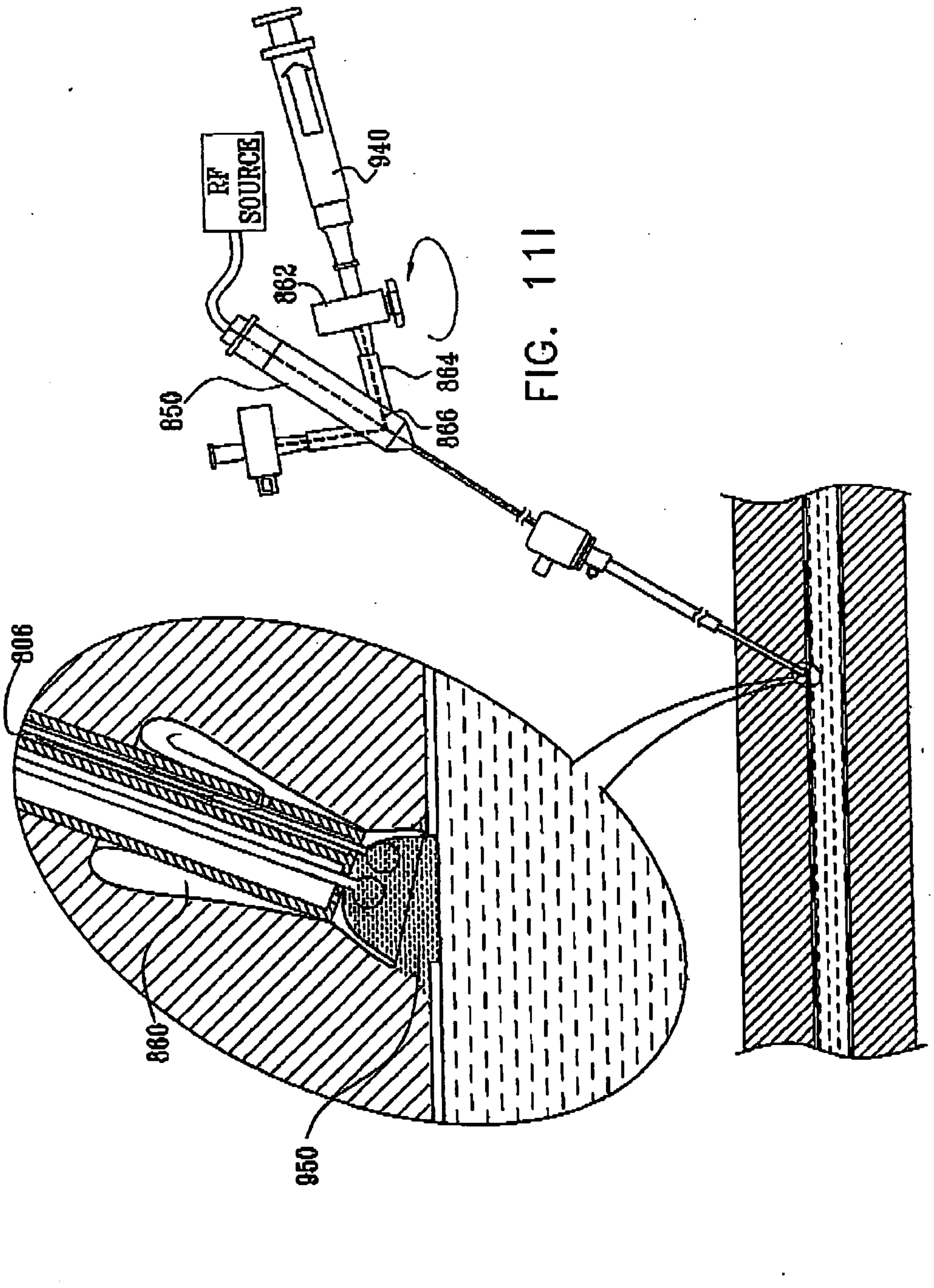


FIG. 11I

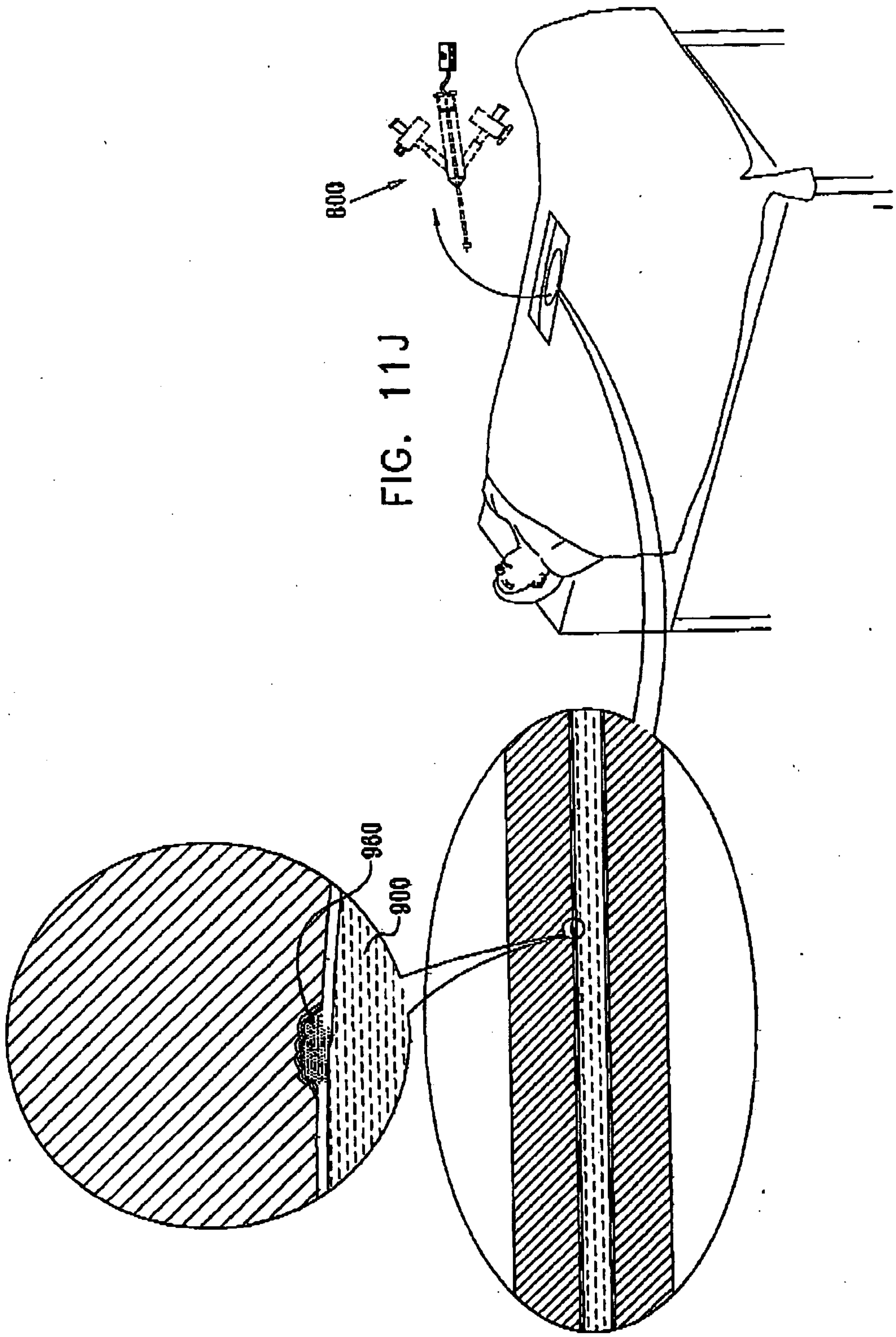


FIG. 11J

FIG. 12A

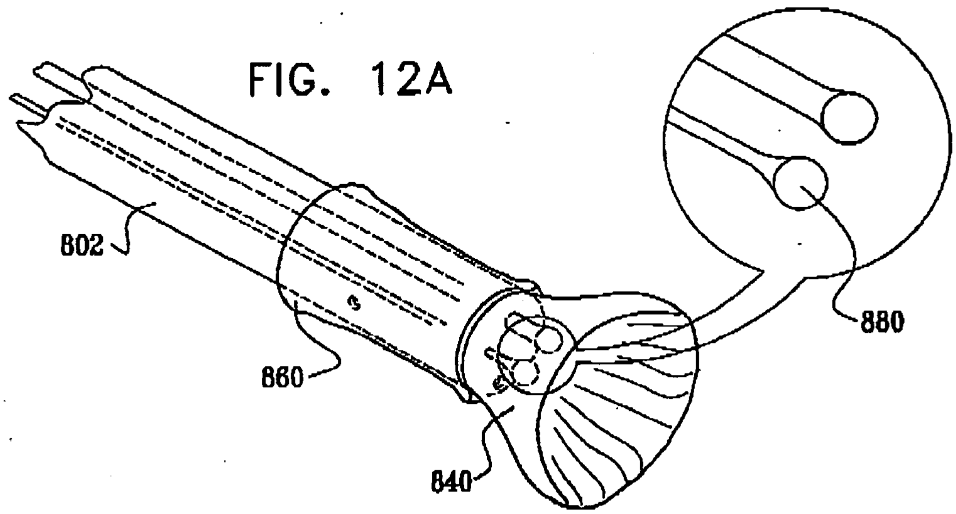


FIG. 12B

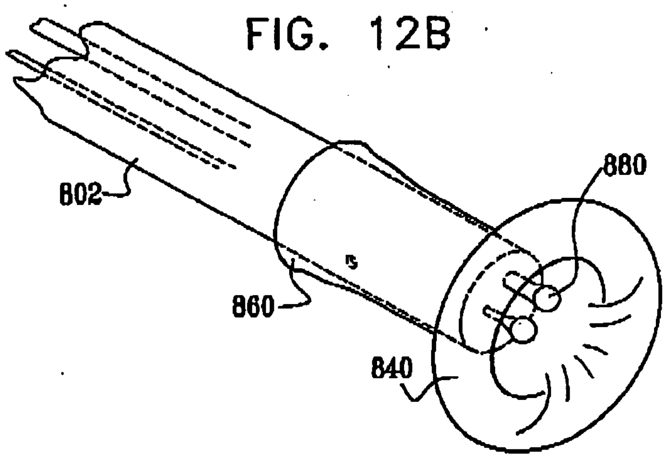


FIG. 12C

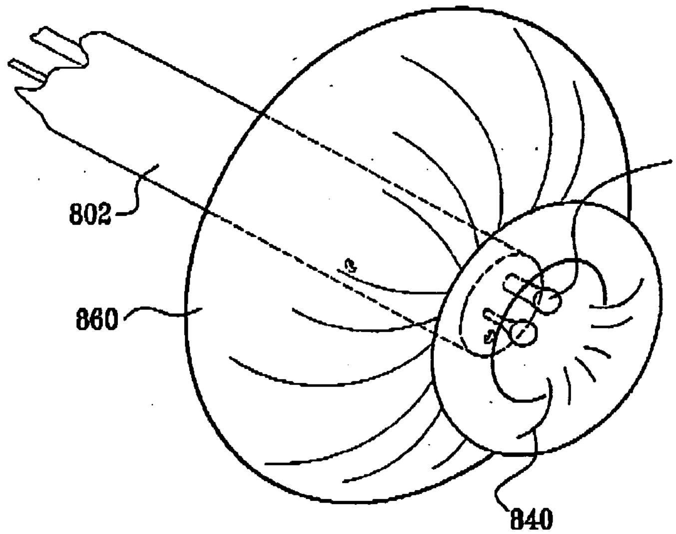
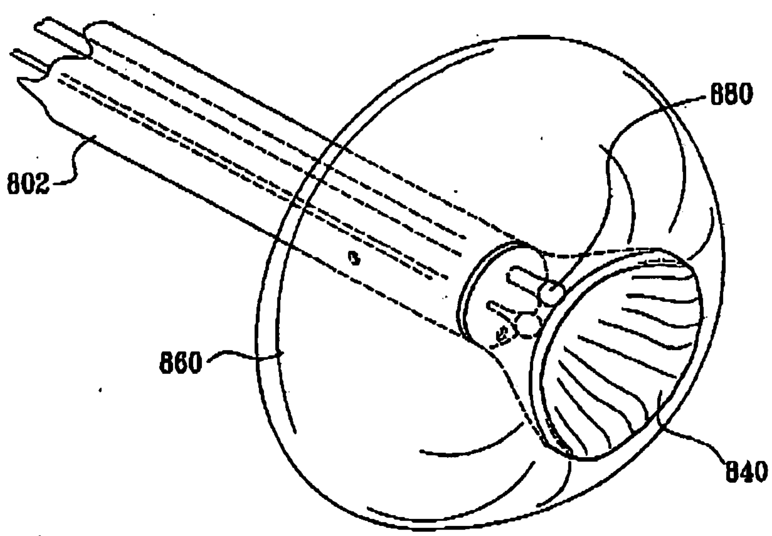


FIG. 12D



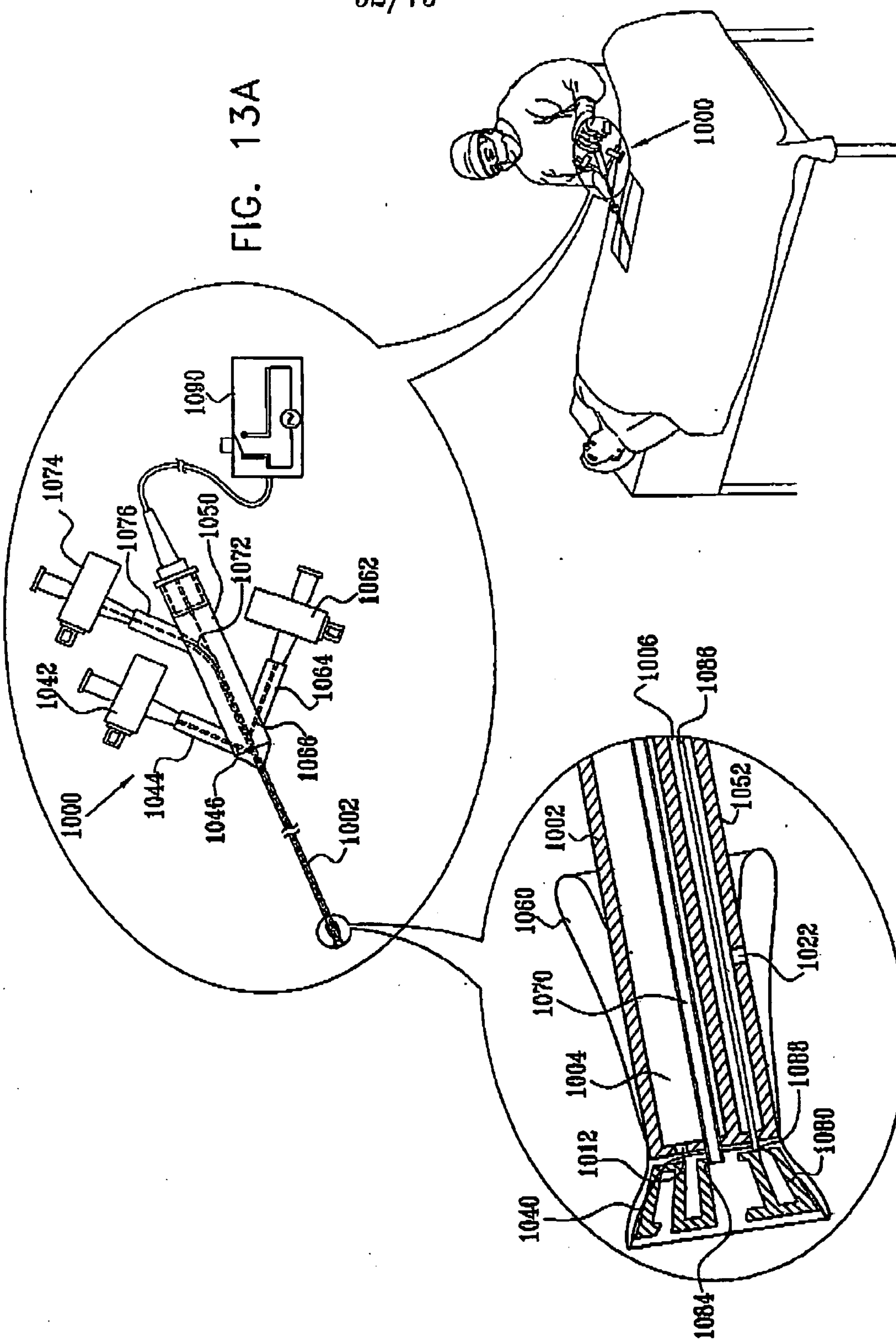

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FIG. 13A

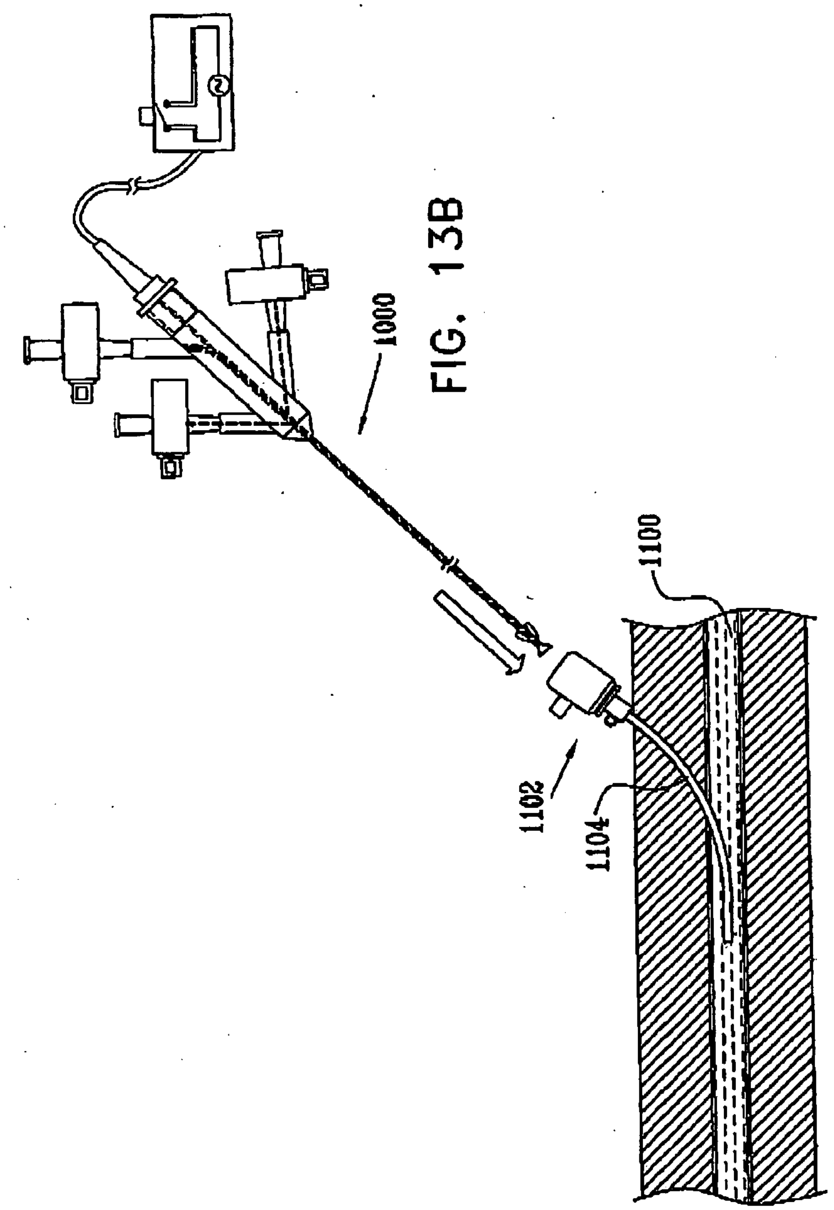


FIG. 13B

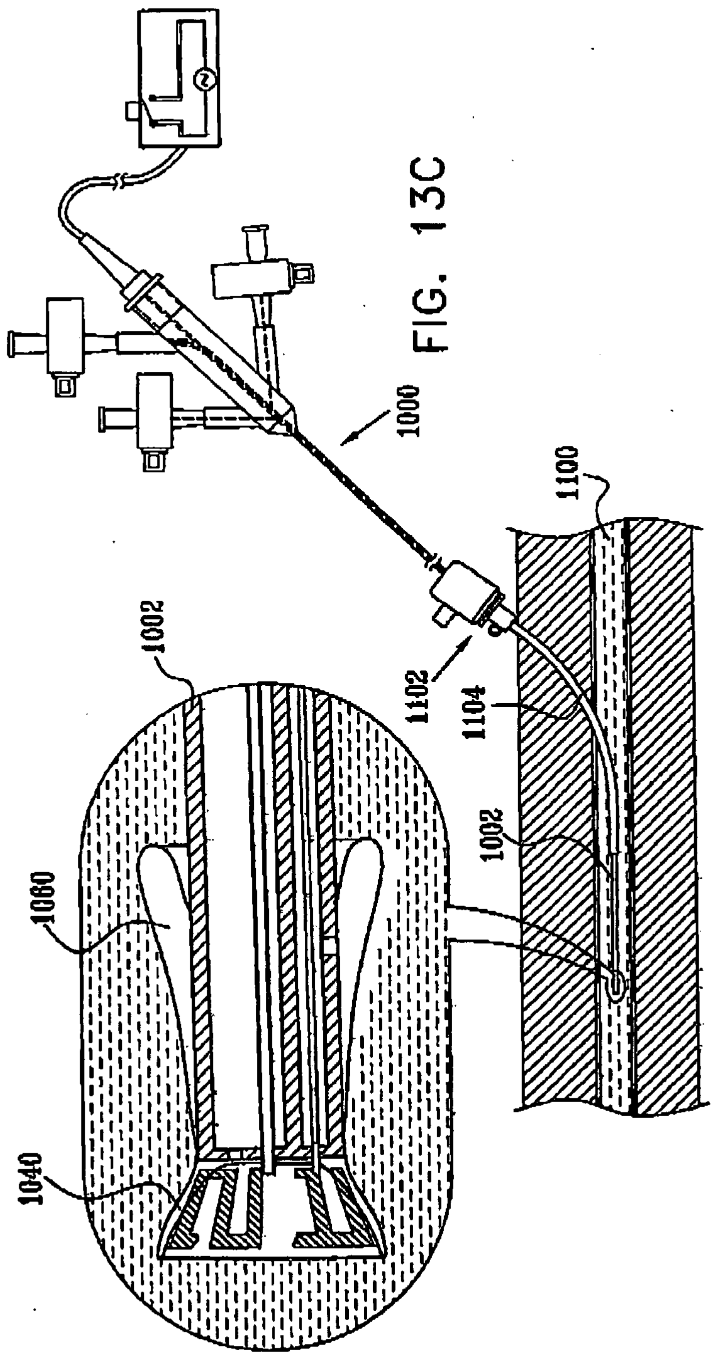


FIG. 13C

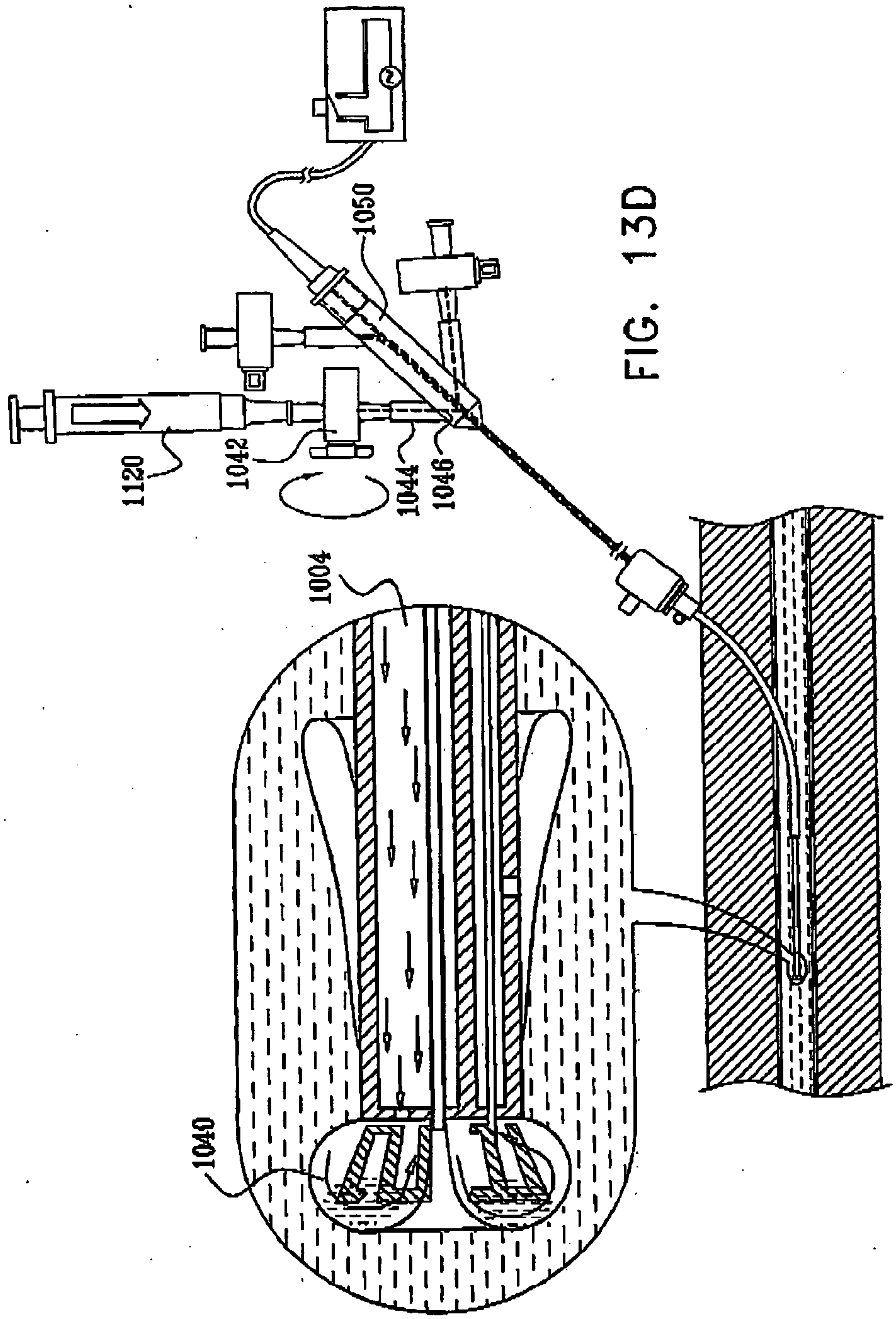


FIG. 13D

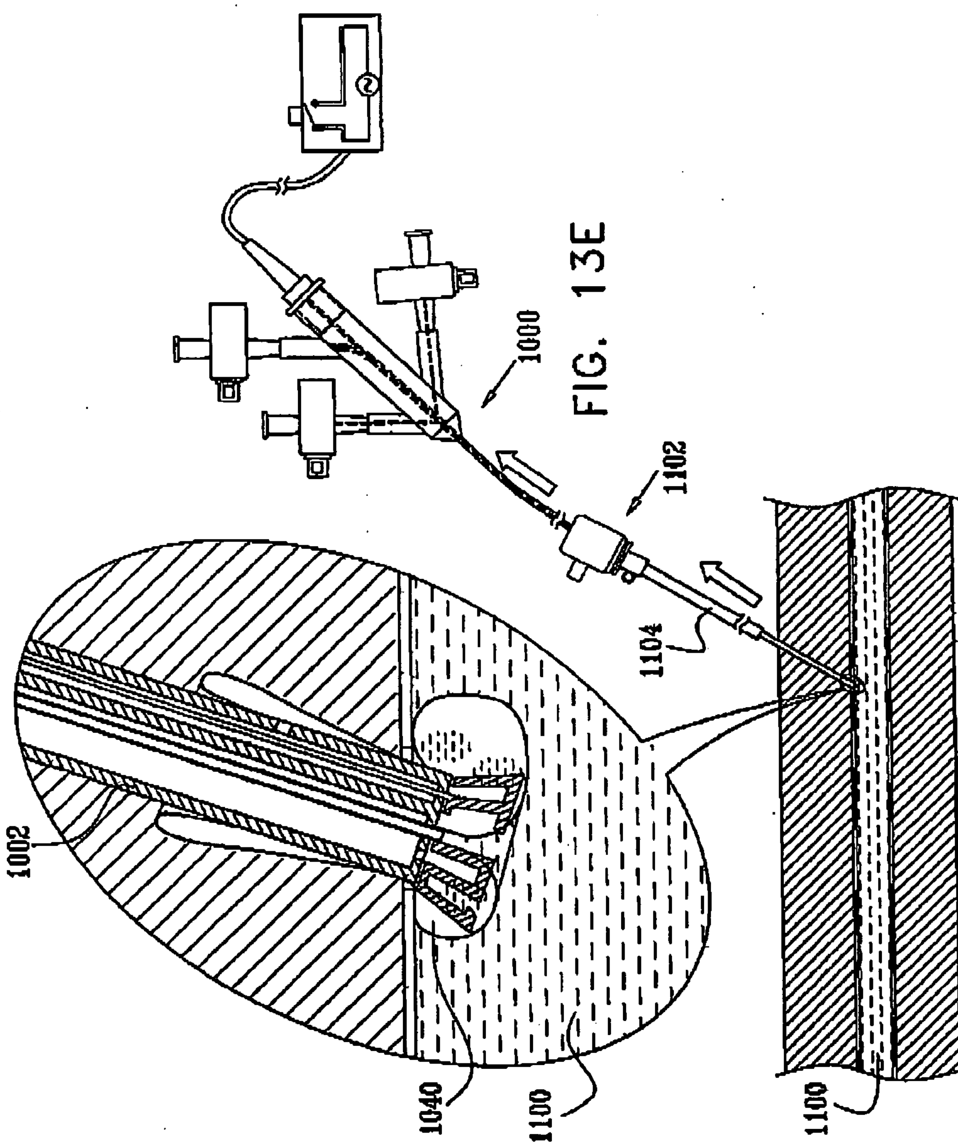


FIG. 13E

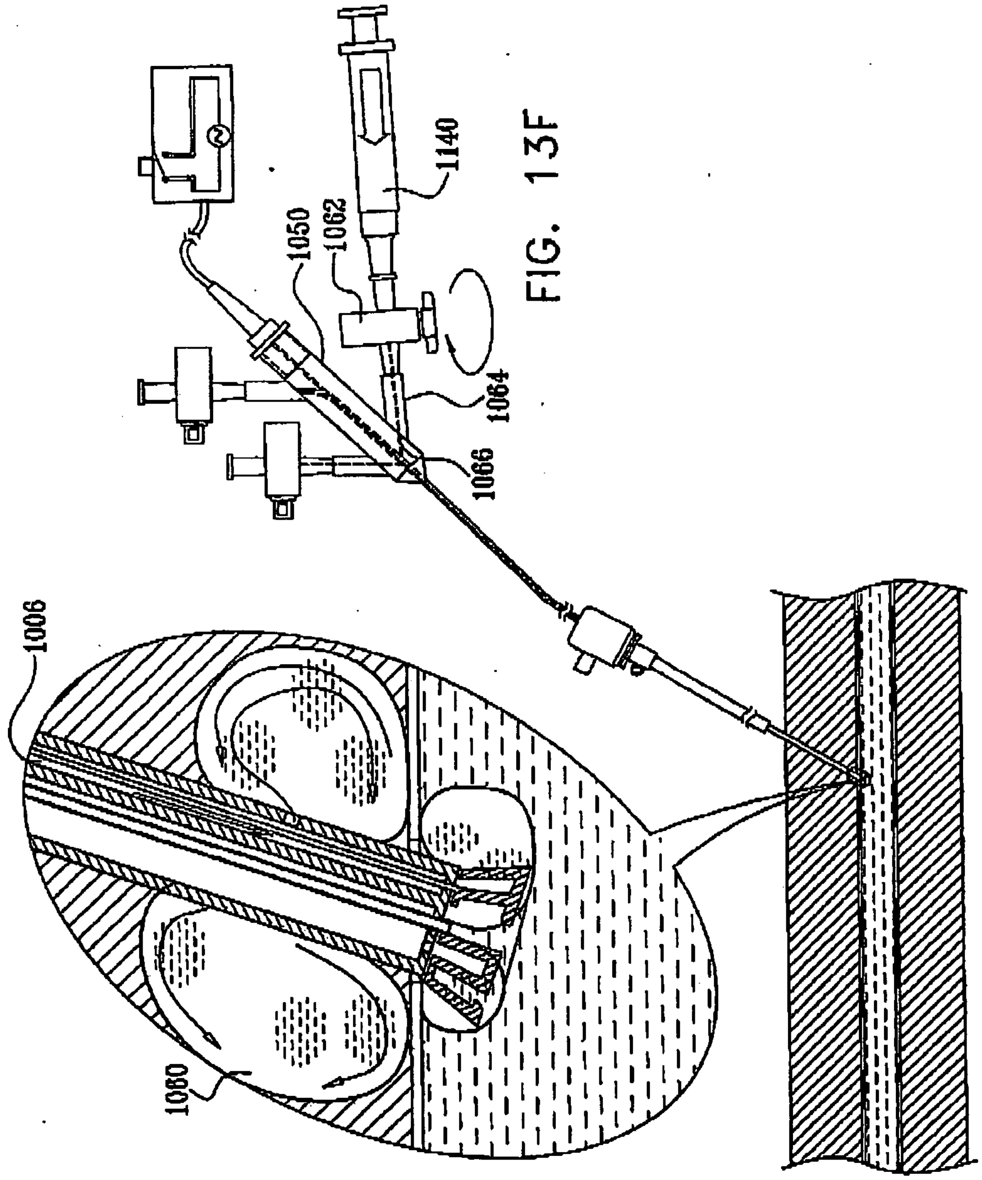


FIG. 13F

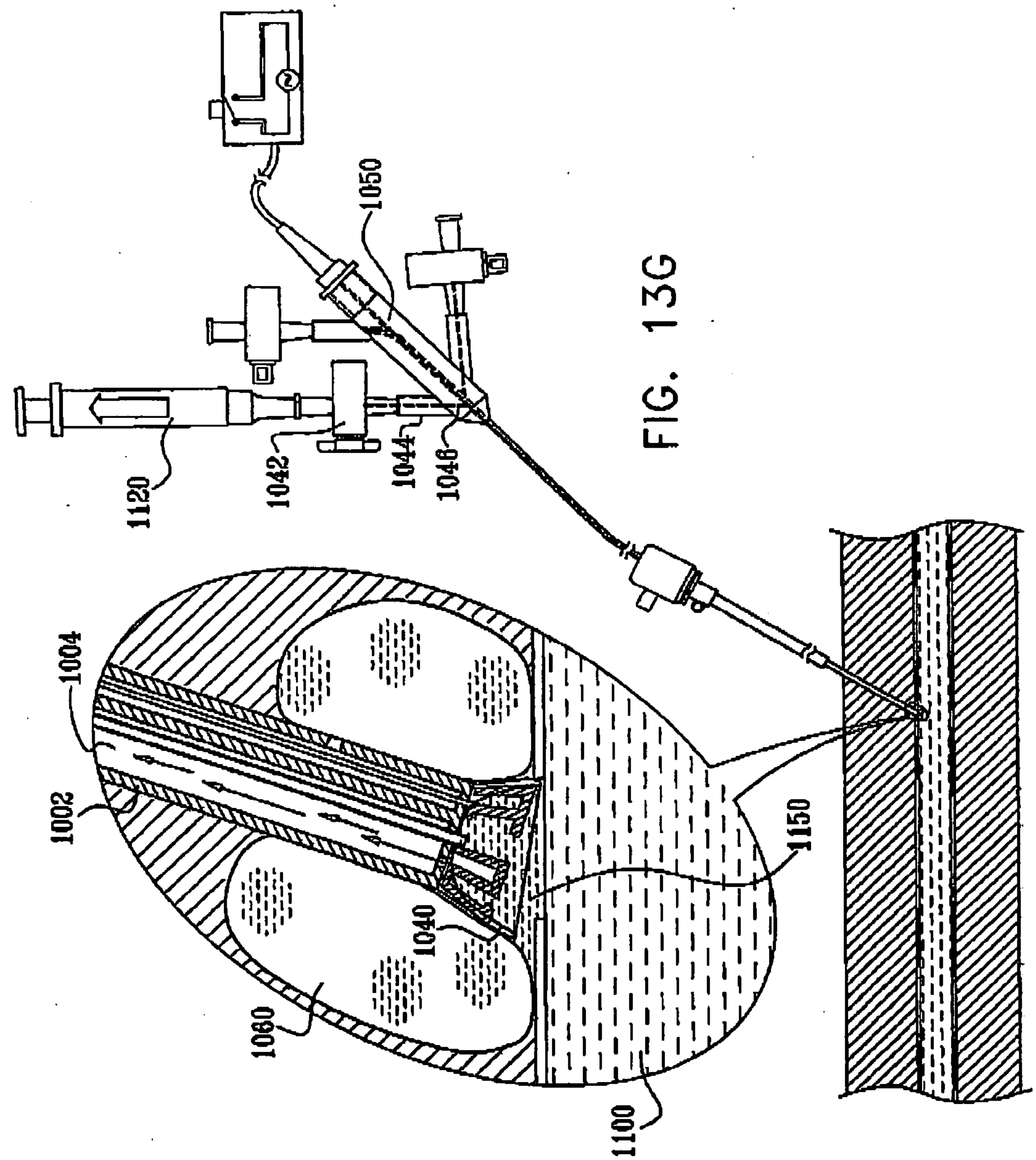


FIG. 13G

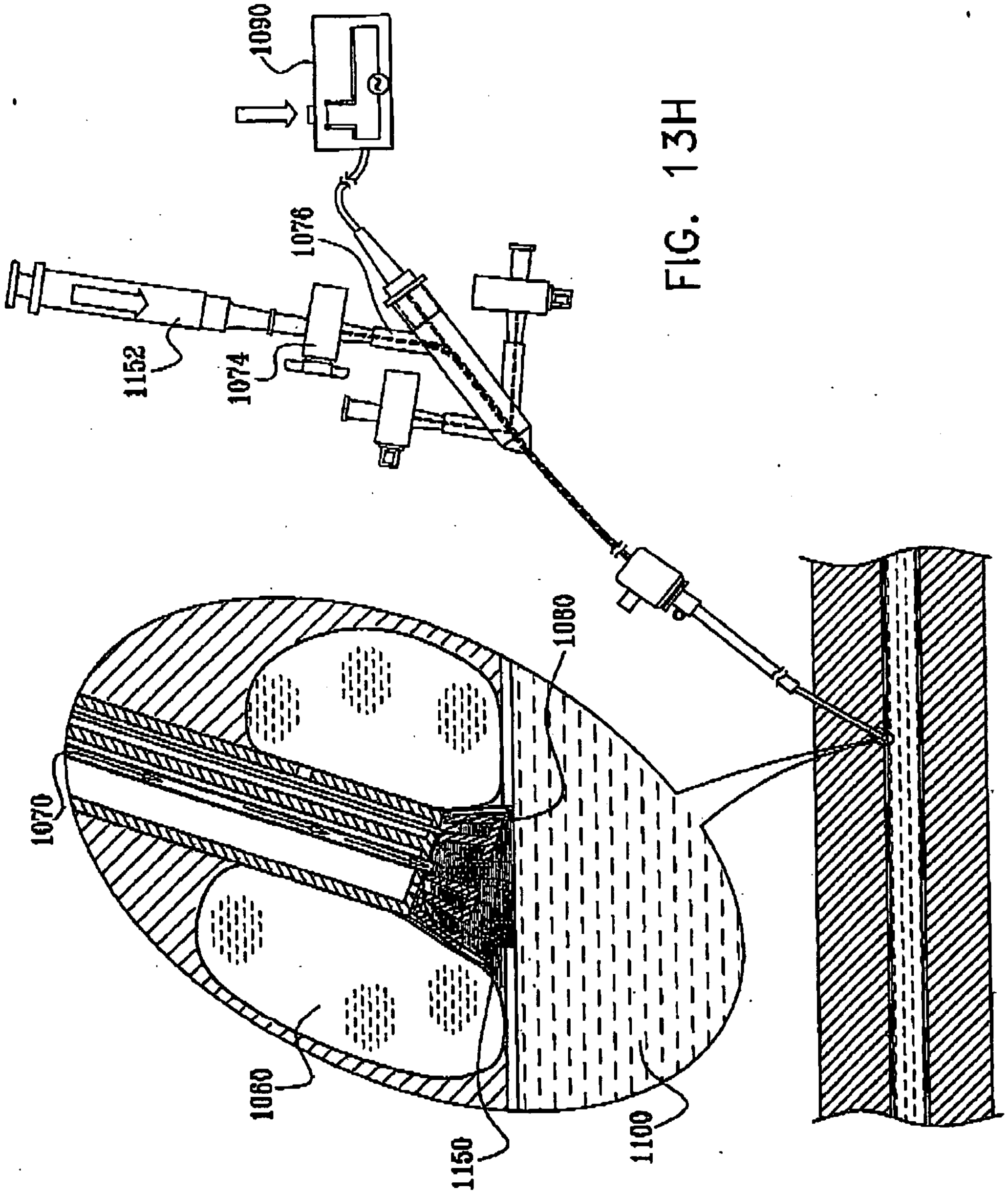


FIG. 13H

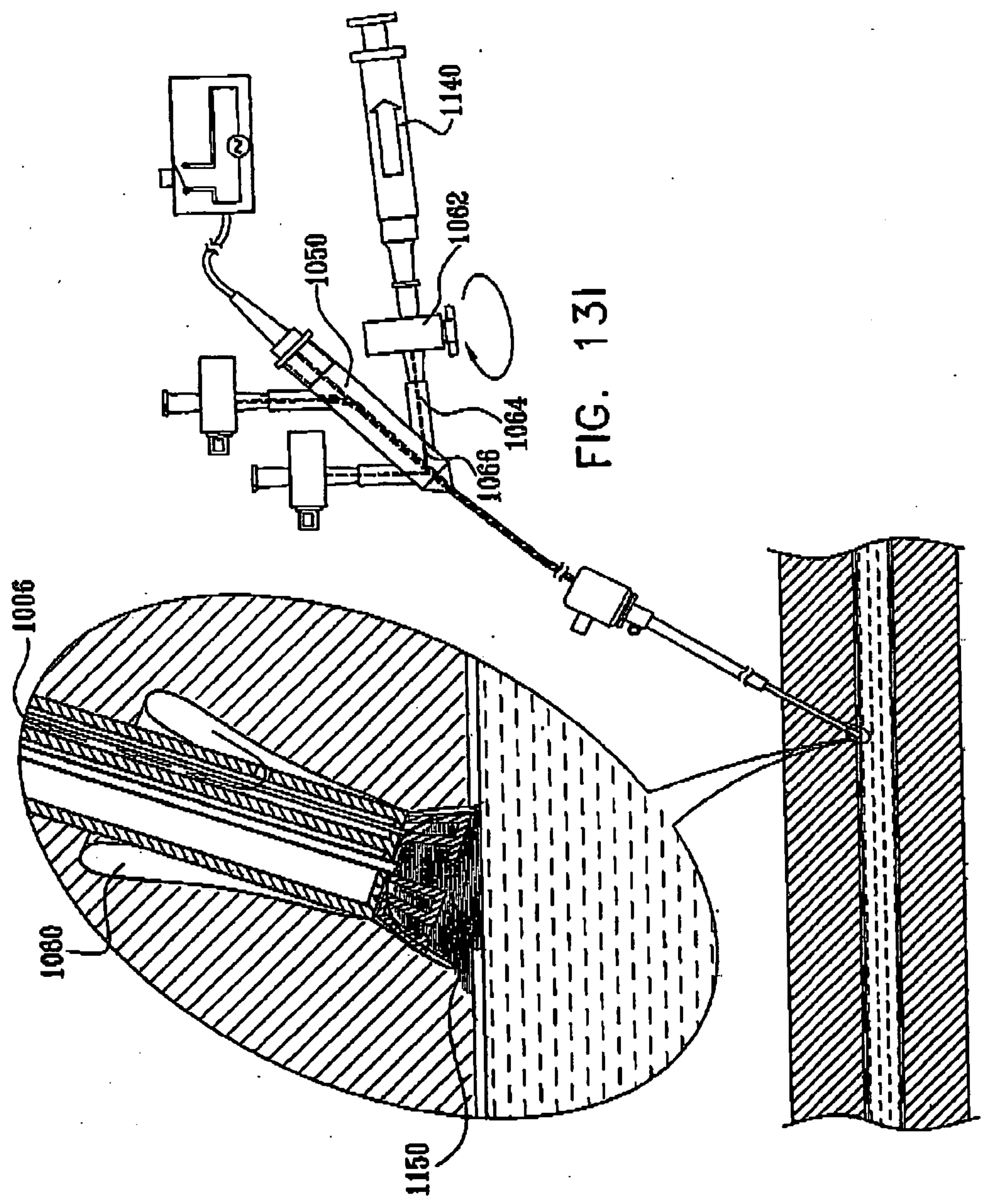


FIG. 13I

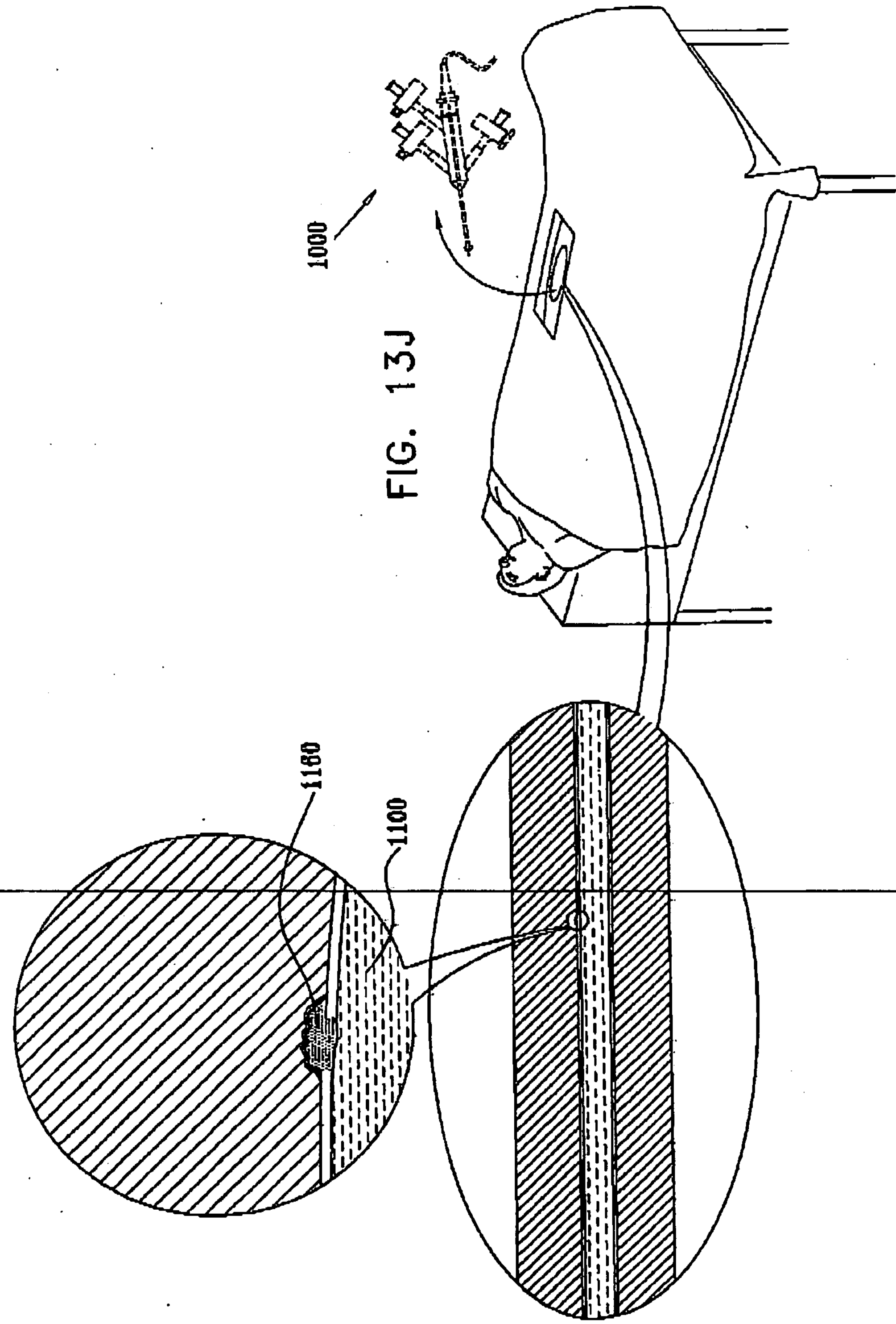


FIG. 13J

FIG. 14A

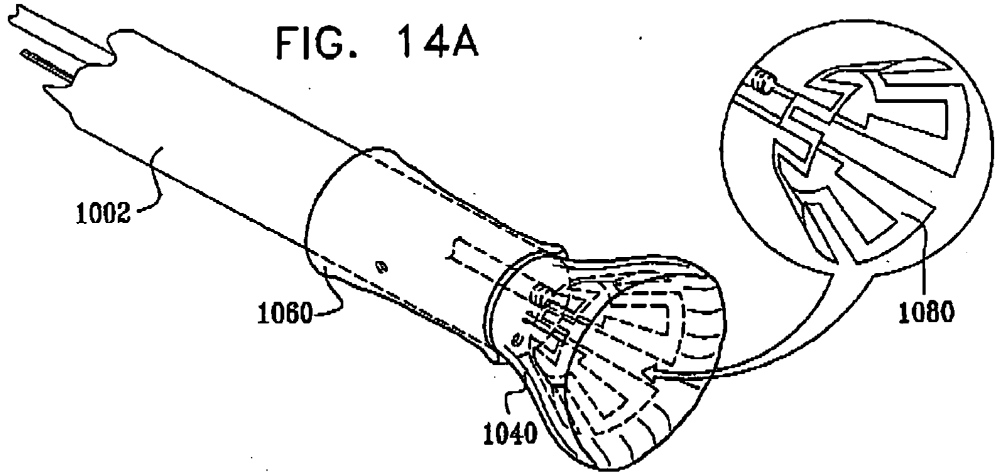


FIG.14B

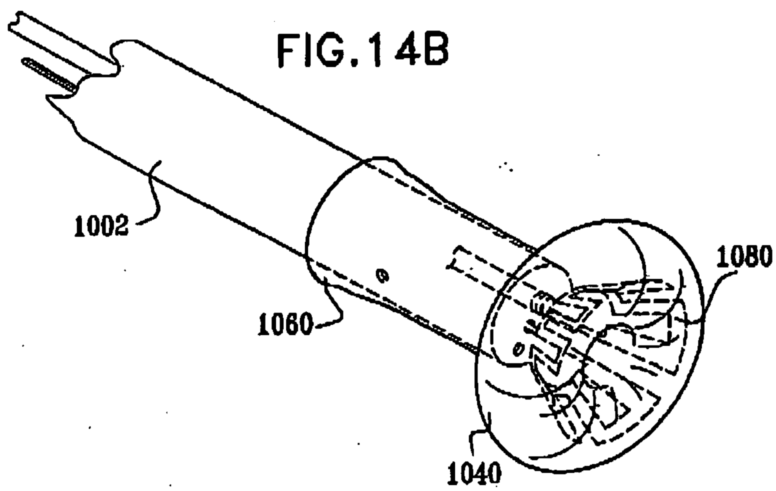


FIG. 14C

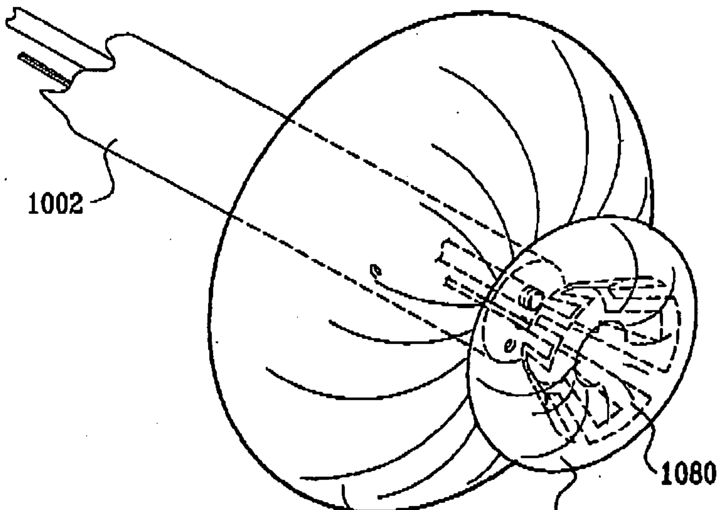
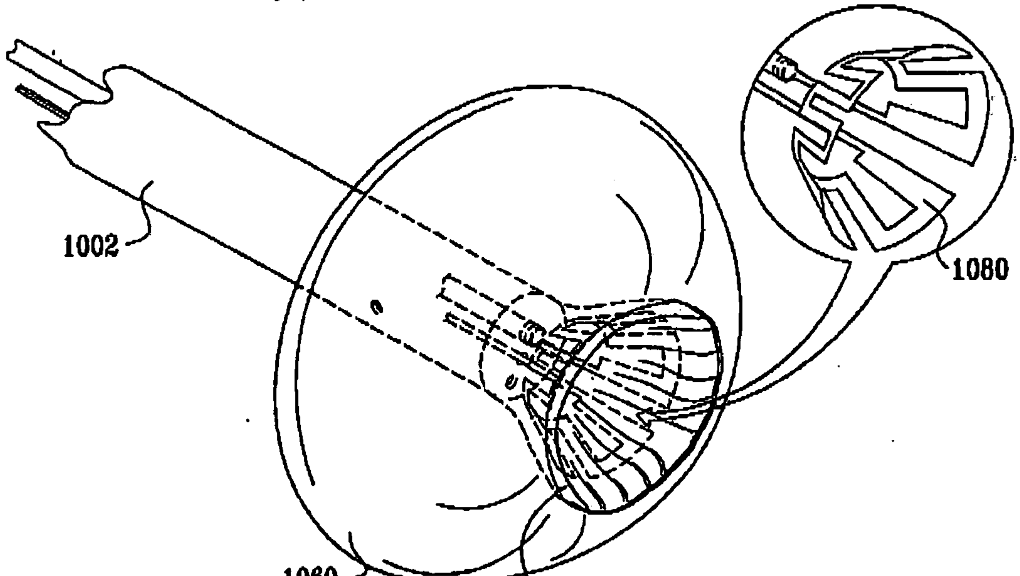
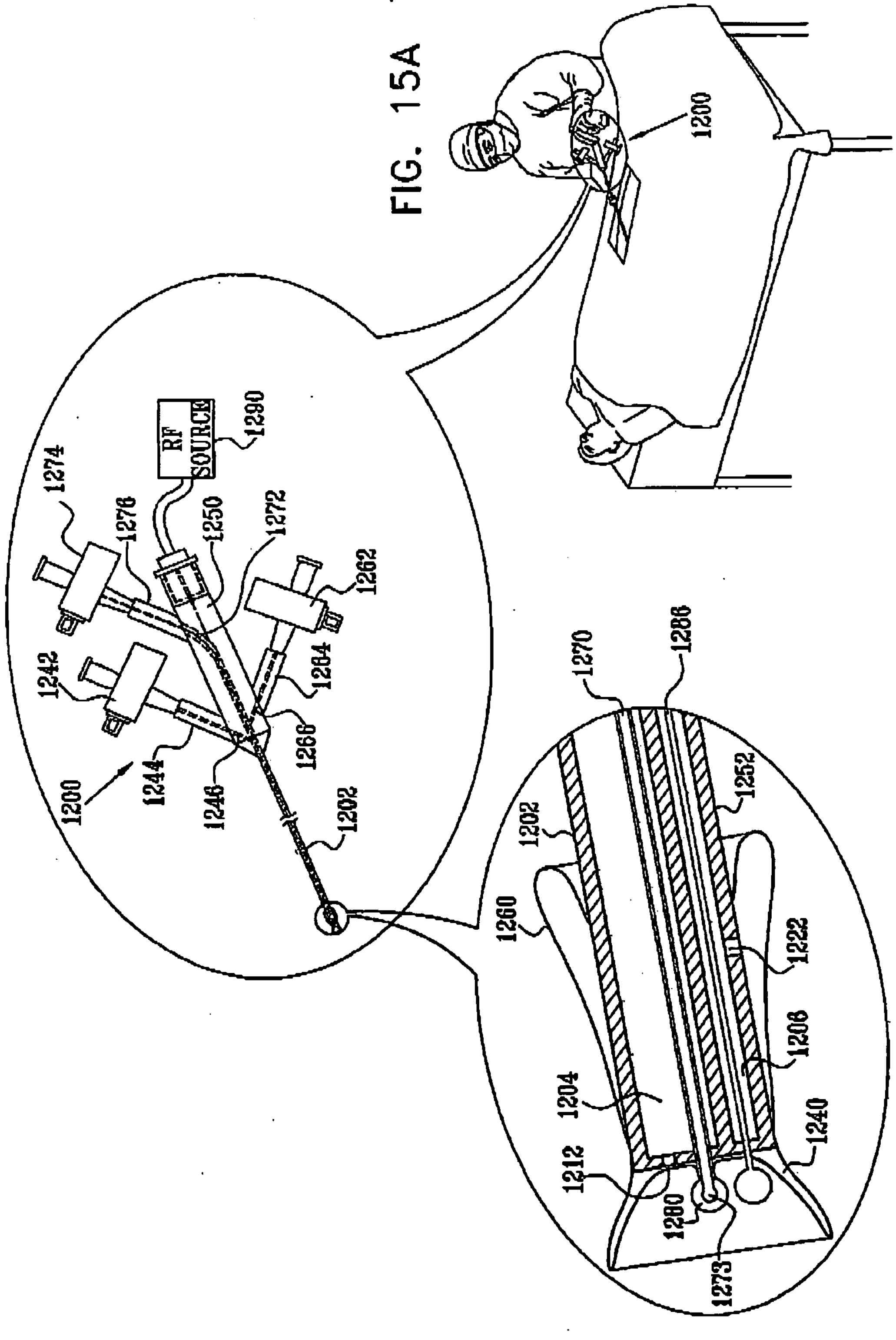


FIG. 14D




1200
RF SOURCE
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1264
1244
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1202
1270
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1252
1260
1222
1206
1204
1240
1212
1280
1273

FIG. 15A

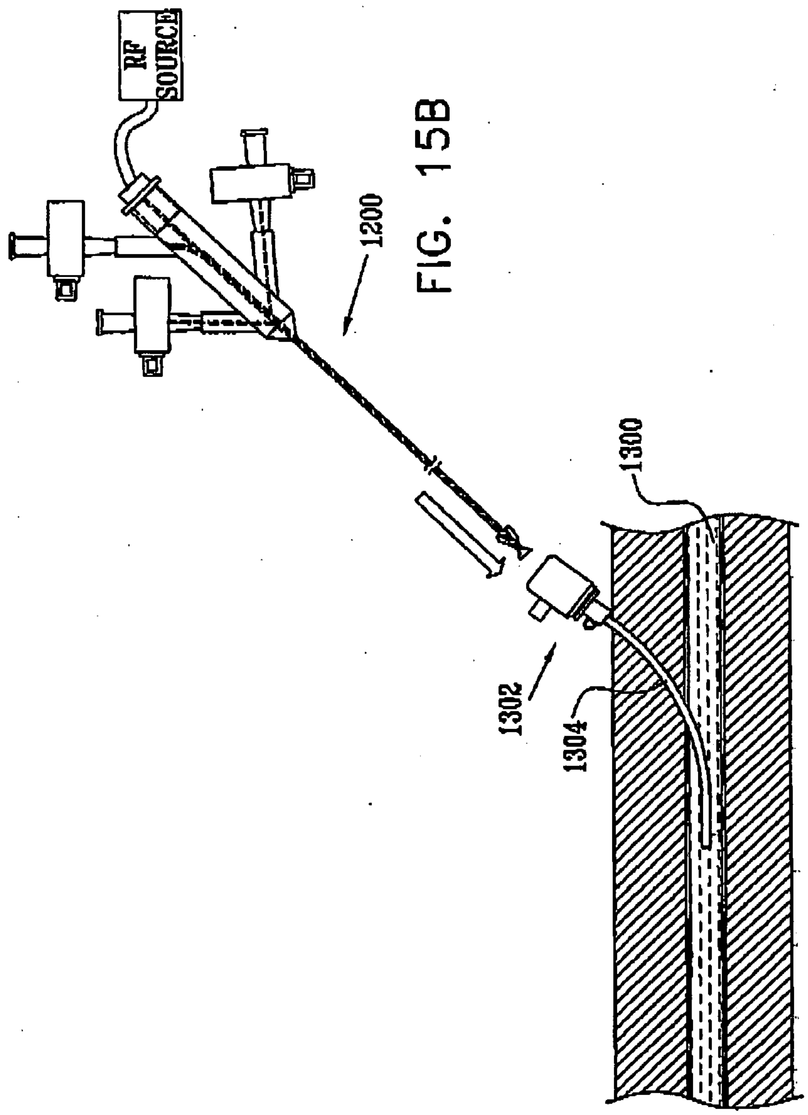


FIG. 15B

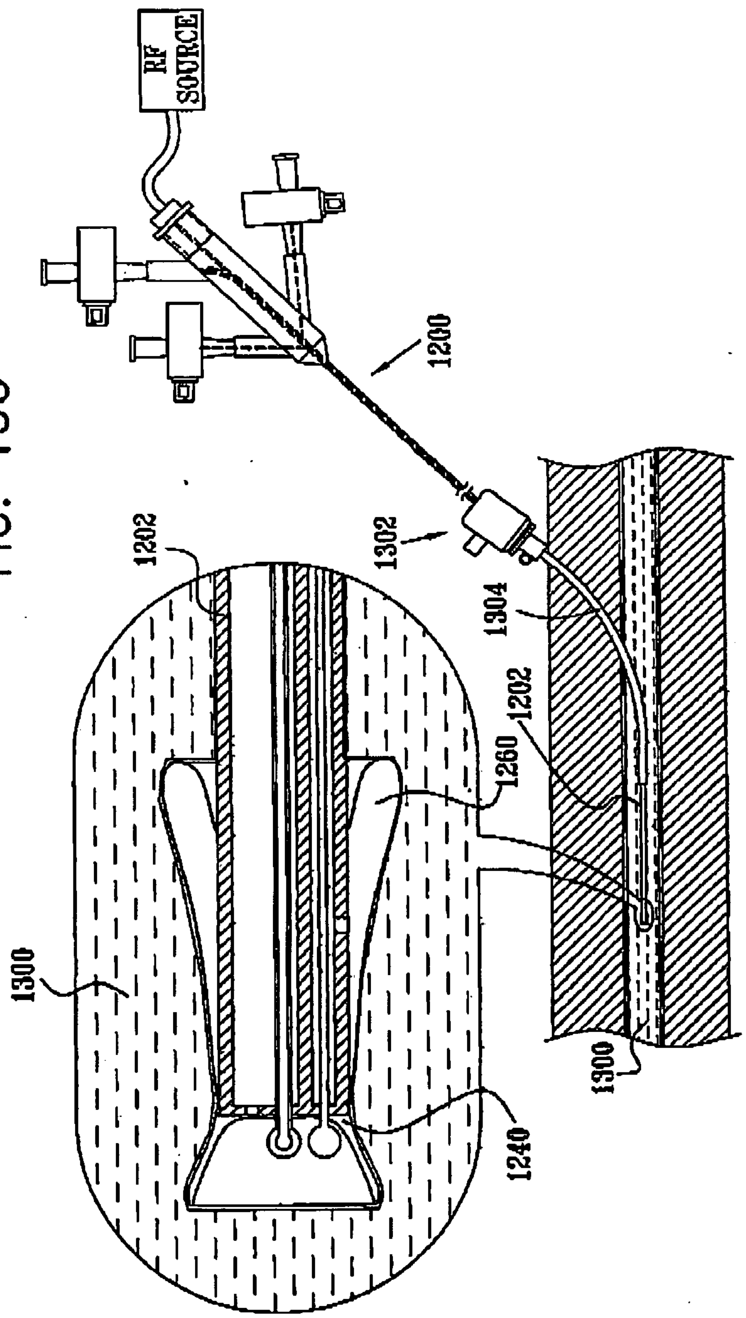


FIG. 15C

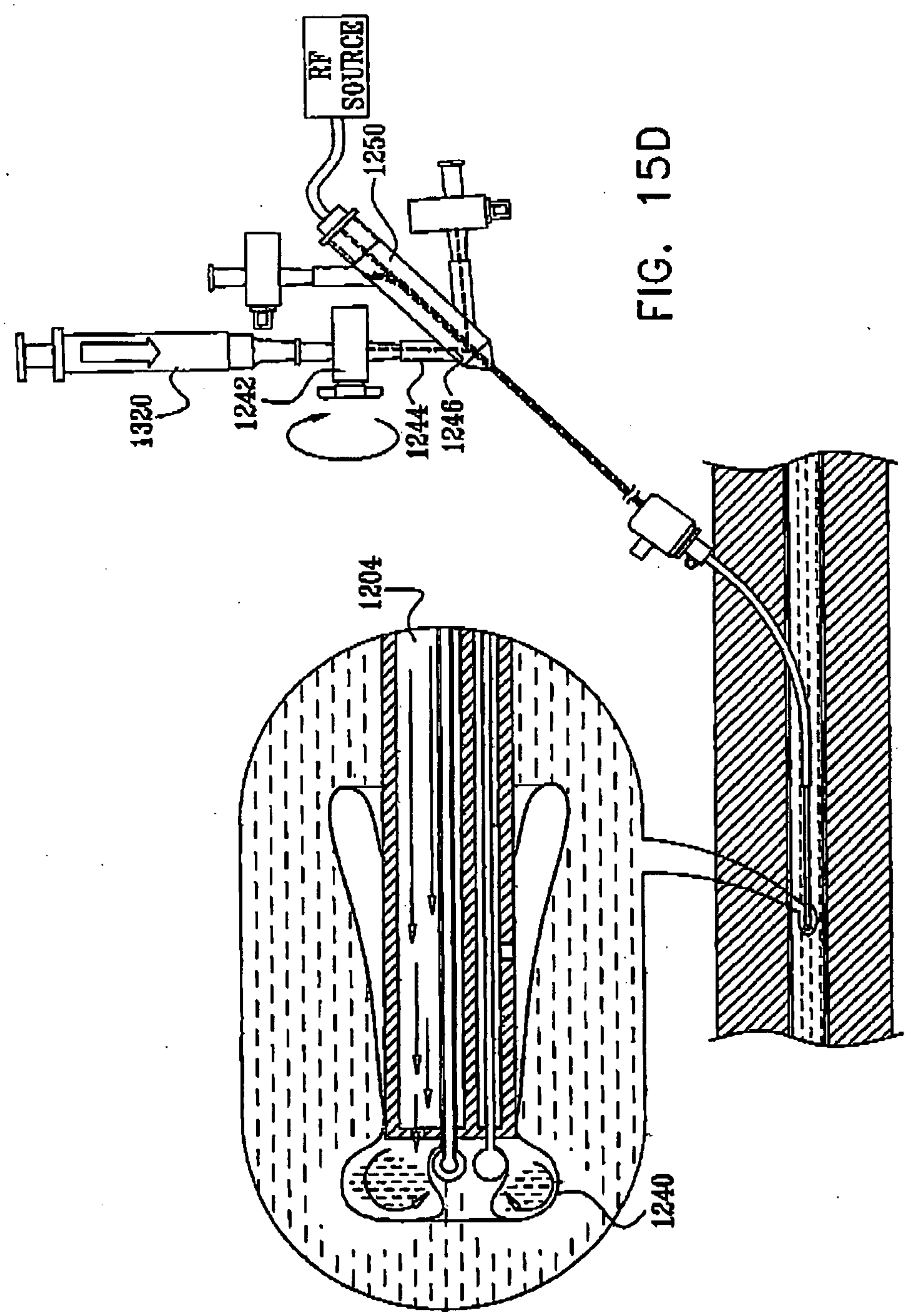


FIG. 15D

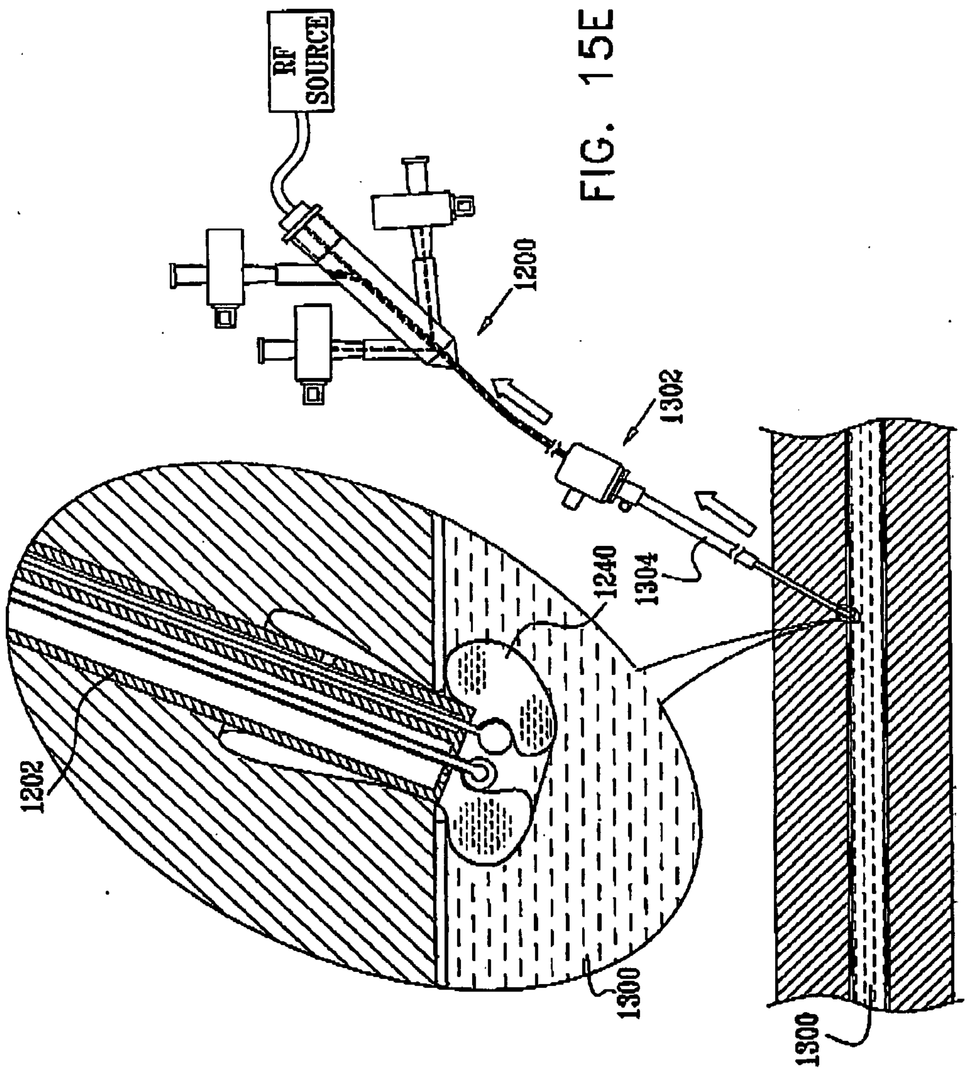


FIG. 15E

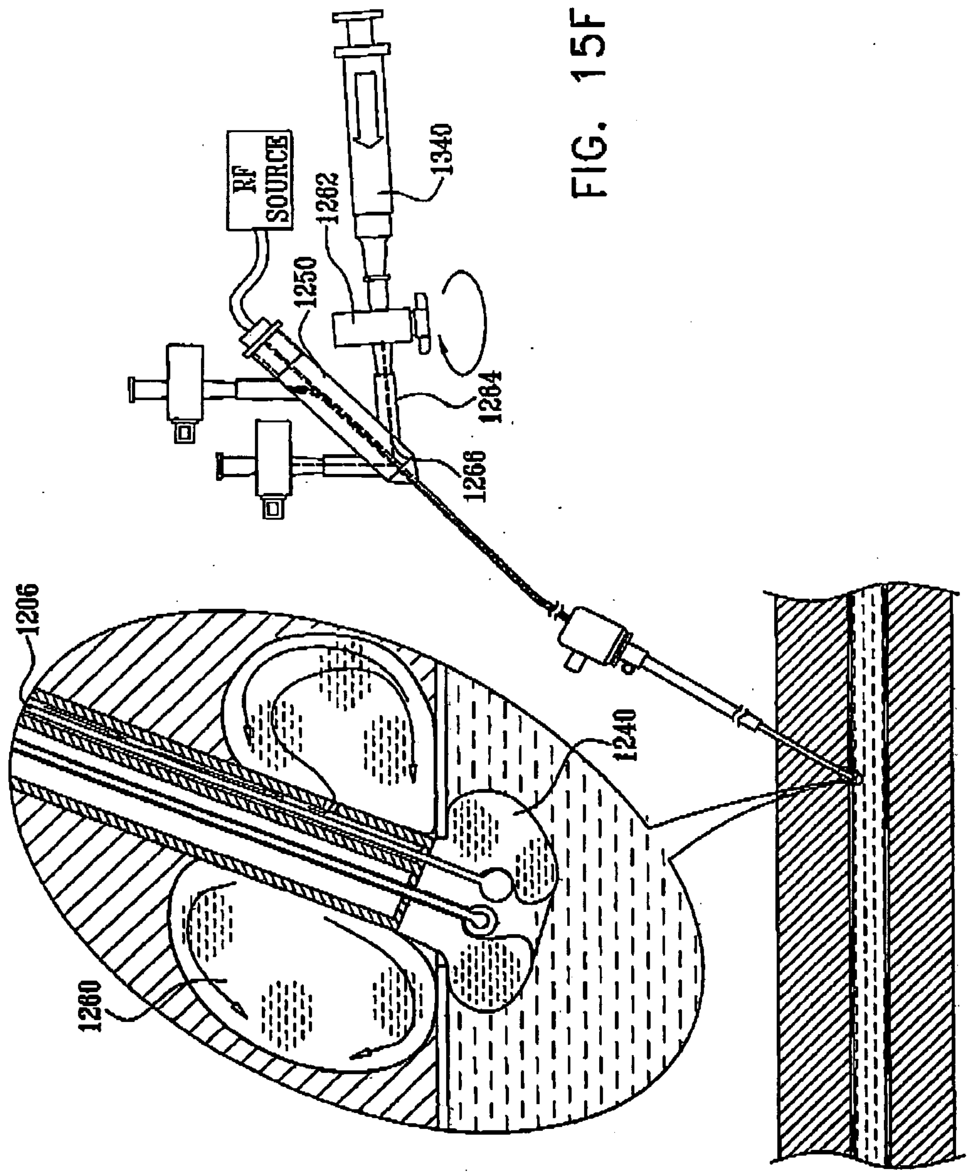
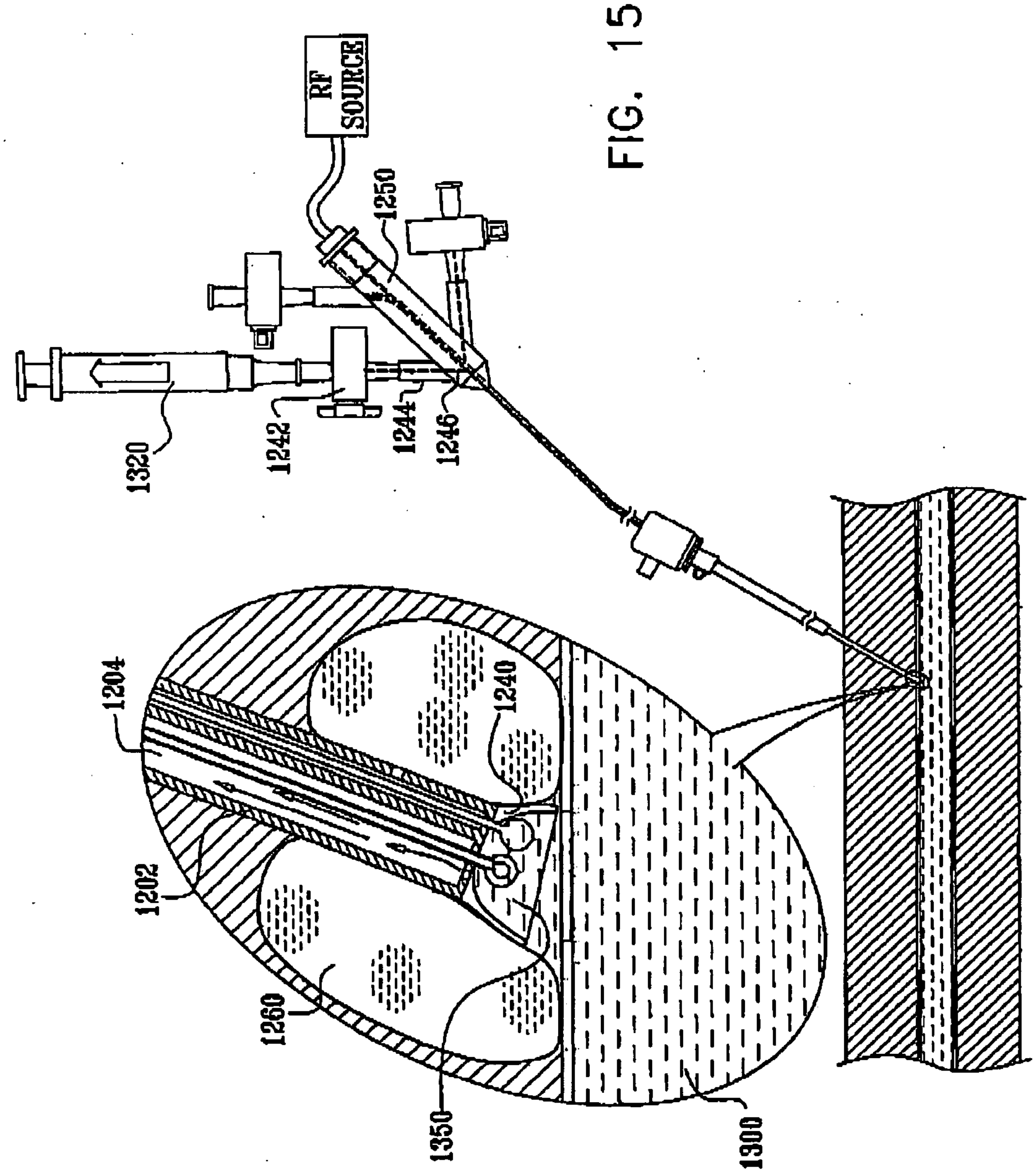


FIG. 15F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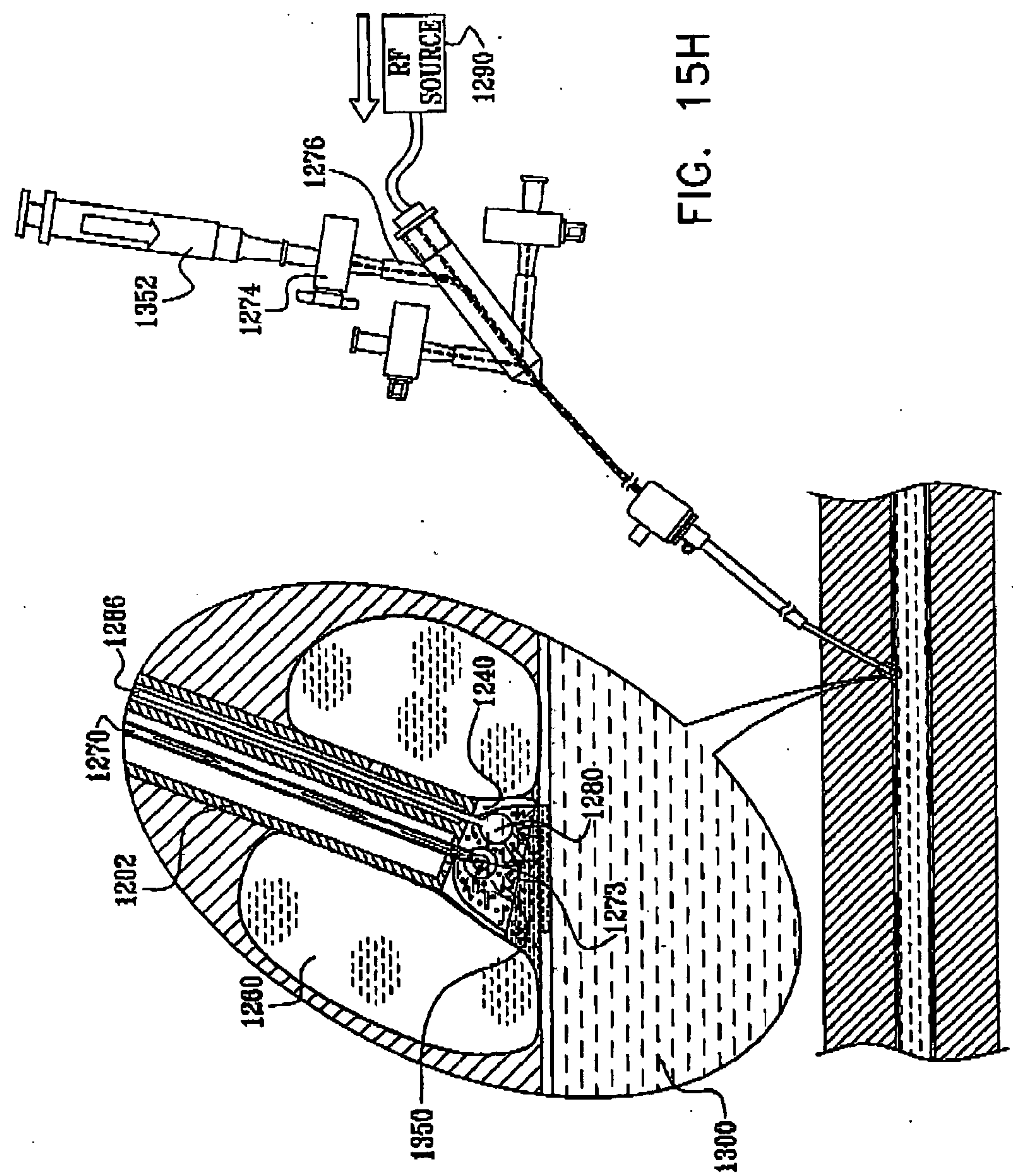
1240
1202
1260
1350
1300

FIG. 15G


RF SOURCE
1290
1276
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1274
1286
1270
1240
1280
1202
1273
1260
1950
1300

FIG. 15H

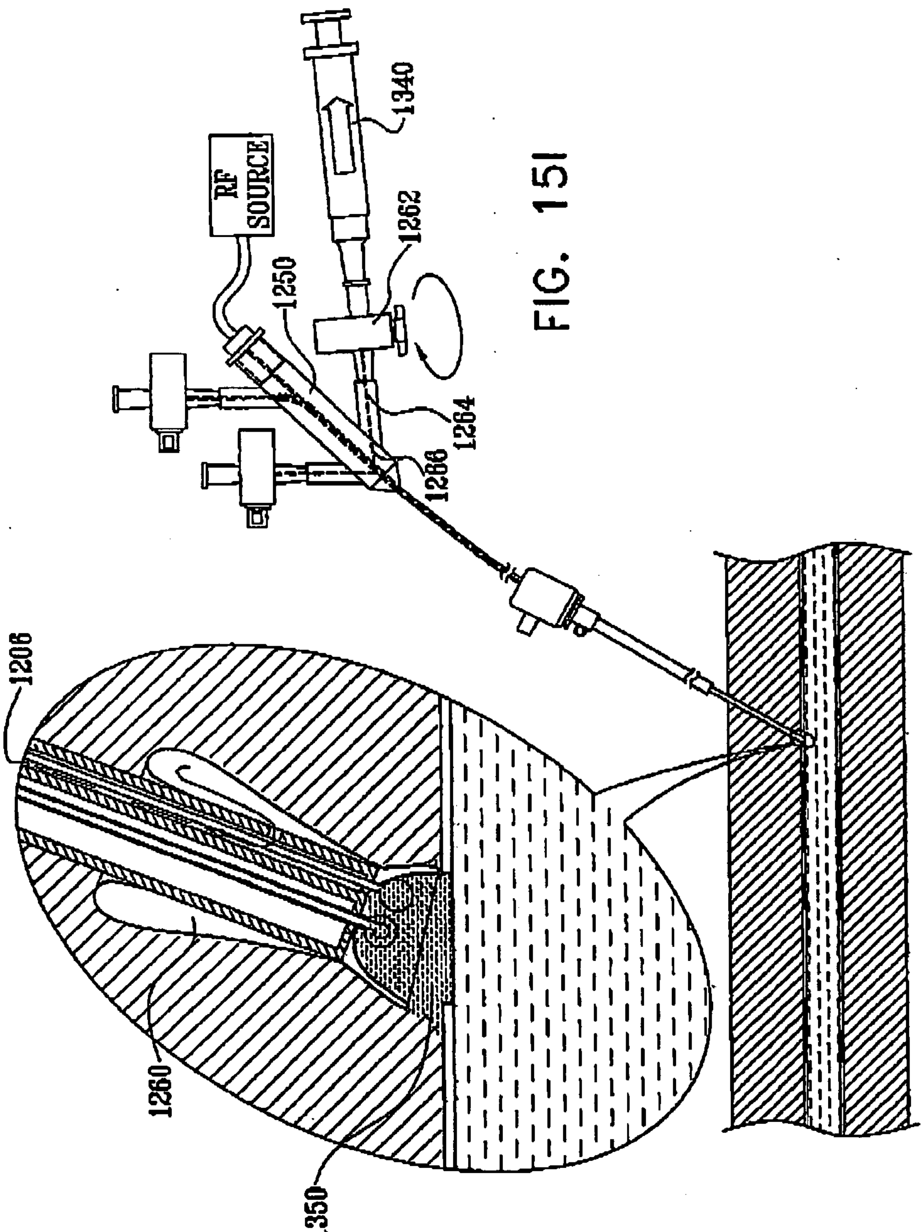

FIG. 15I

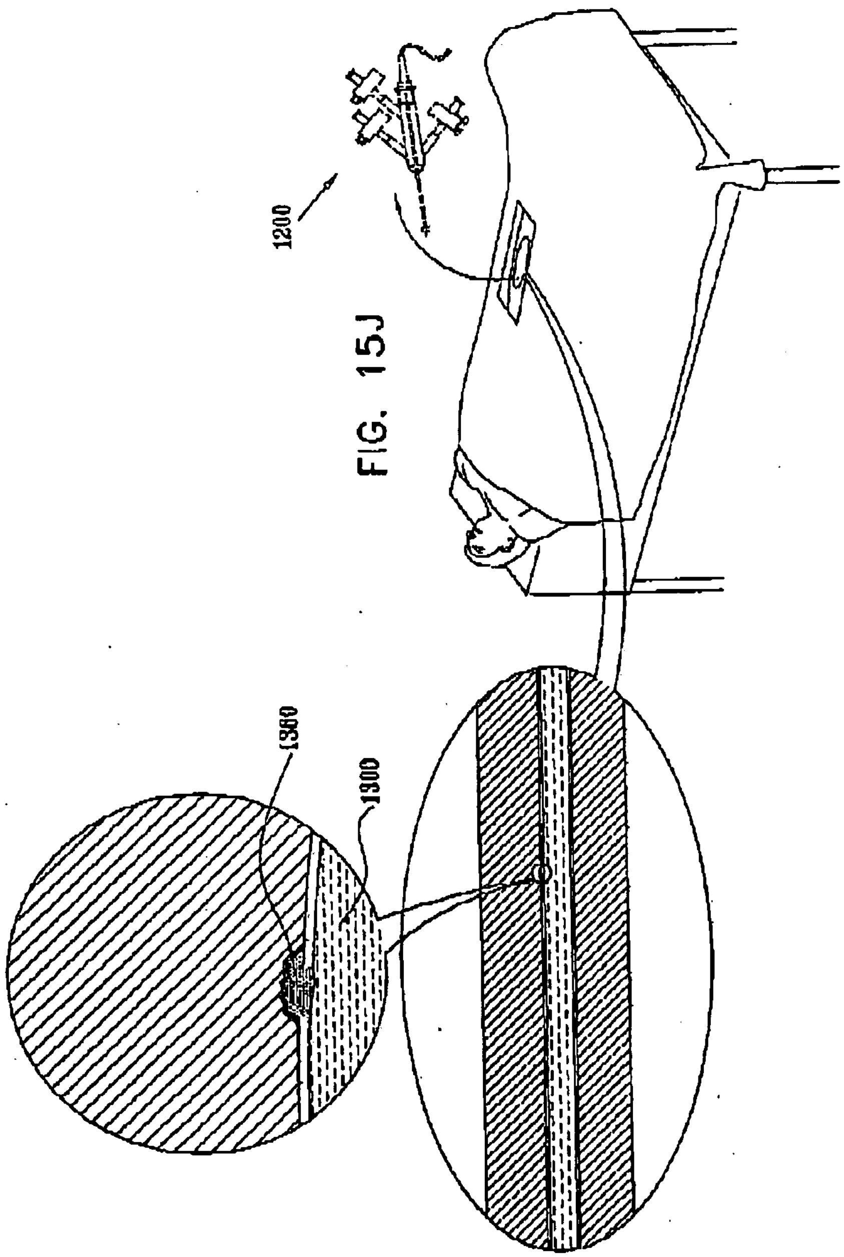

FIG. 15J

FIG. 16A

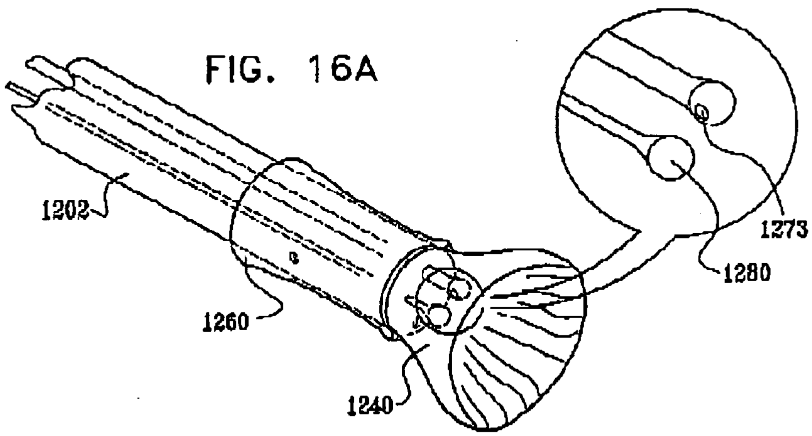

FIG. 16B

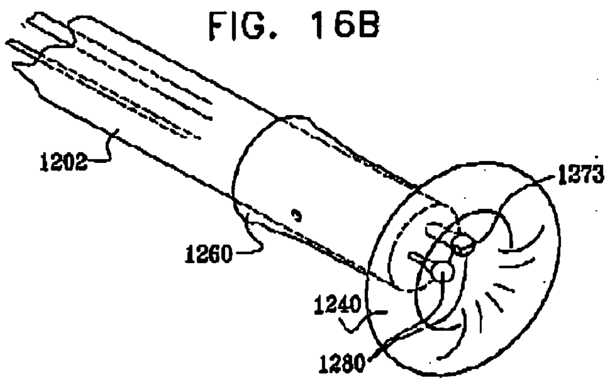

FIG. 16C

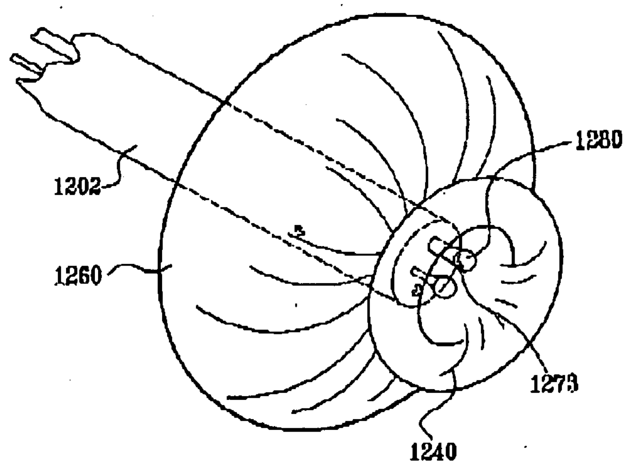

FIG. 16D